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FOREWORD

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OHTA is part of the National Center for Health Services Research and Health Care Technology Assessment (NCHSR), Public Health Service, Department of Health and Human Services.

Enrique D. Carter, M.D.
Director, Office of Health
Technology Assessment

J. Michael Fitzmaurice, Ph.D.
Director, National Center for
Health Services Research and
Health Care Technology Assessment

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Publications and Information Branch
NCHSR
Parklawn Building, Room 18-12
5600 Fishers Lane
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Abstract

Cardiac rehabilitation services are comprehensive long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. These programs are designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients. Cardiac rehabilitation services are prescribed for patients who 1) have had a myocardial infarction; 2) have had coronary bypass surgery; or 3) have chronic stabile angina pectoris. The services are in three phases beginning during hospitalization followed by a supervised ambulatory outpatient program lasting 3-6 months, and continuing in a lifetime maintenance stage in which physical fitness and risk factor reductions are accomplished in a minimally supervised or unsupervised setting. There are no uniform standards for these services. Data suggest that three weekly 1 hour exercise sessions for 12 weeks yield physiologic benefits. Routine electrocardiographic monitoring during exercise is necessary only in exceptional cases. A consensus of opinion suggests that these programs improve the function and symptomatic status of selected patients and are associated with little risk of adverse events.

PUBLIC HEALTH SERVICE ASSESSMENT

CARDIAC REHABILITATION SERVICES

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INTRODUCTION

Cardiac rehabilitation services are intended to restore certain patients with coronary heart disease to active and productive lives. A comprehensive long-term program of medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling is encompassed, but there is considerable variability in supervision, emphasis, and content among providers. Cardiac rehabilitation programs have occasionally enrolled patients with other forms of heart disease, or asymptomatic individuals with elevated risk factors for coronary heart disease. Nevertheless, rehabilitation services are typically designed for patients recovering from an acute myocardial infarction, coronary artery bypass graft (CABG) surgery, or with chronic stable angina pectoris (1).

The goal of cardiac rehabilitation emphasizes the attainment of an optimum state of health for each patient by means of a multifactorial program (2). Specific objectives include limiting the physiologic and psychological effects of cardiac illness, reduction of risk for sudden death or reinfarction, medical or surgical control of symptoms, stabilization or reversal of the atherosclerotic process, as well as enhancement of psychosocial and vocational status (1).

BACKGROUND

Coronary heart disease has been estimated to afflict 5.7 million Americans (3). It is the major cause of mortality after age 40 in men and after age 50 in women, representing over 650,000 deaths annually (4). The incidence of myocardial infarction in the United States is about 1.5 million events each year with one-third of that number due to reinfarctions (5). Coronary artery bypass grafts were performed in 170,000 Americans during 1982 as a direct result of coronary heart disease (5). In women angina is the most likely initial heart manifestation, whereas in men myocardial infarction or sudden death are the most likely initial experiences (3). Overall, only 20 percent of infarcts are preceded by chronic angina. Angina is considered "unstable" when it occurs unpredictably without provocation as contrasted with "stable" angina, which tends to occur predictably in response to exertion (4). Cardiac exercise testing is one way of identifying stable angina. Patients with stable angina compose one-fourth of the coronary population. In persons under age 65, about 80 percent of mortality due to myocardial infarction occurs during the first attack (3). For that reason most coronary deaths befall people with no prior history of symptomatic cardiac ischemia. During the first year following an infarct, 20 percent of men and 45 percent of women expire. Overall, 70-80 percent of these deaths occur during the first 24 hours following a heart attack (4). Survival has been linked to the location and extent of the infarcted area as well as the degree of ventricular impairment and the number of coronary vessels involved. Various methods for classifying coronary heart disease patients into high- and low-risk groups have been developed employing anatomic data in conjuction with the results of

exercise stress testing (1,4). Graded exercise testing 1-3 weeks after a myocardial infarction has been recommended to establish a patient's activity limits and provide prognostic information (1).

The clinical management of patients with "uncomplicated" myocardial infarction has evolved to a point where early ambulation, resumption of physical exertion, and a normal pace of daily existence are routinely encouraged. These are understood to be patients without serious or recurrent arrhythmias, shock, persistent pain, or congestive failure (6). Physicians of the 1940s and 50s customarily treated myocardial infarction patients with 4-8 weeks of bedrest, oxygen, and sedation. Return to work was often delayed for 4-6 months. By 1970 a survey of 2,491 physicians who managed 70,000 patients disclosed that hospitalization for uncomplicated myocardial infarction had been reduced to a median stay of 21 days in 95 percent of cases (6). In addition, most respondents restricted smoking and dietary caloric (or other) intake for their patients. Of these postinfarction patients under age 64, 87 percent had returned to work within 2-4 months of the event. Progressive ambulation was usually permitted commencing 1-week after hospital admission, with stair climbing allowed after about 1 month of recovery. Clinical judgment concerning the patients' response to walking and other daily activities was the most common basis for guidance offered in addressing the prudent limits of exercise. Less than one-fourth of the responding physicians employed any standardized exercise test to gauge their patient's functional work capacity. In the absence of exercise testing, an objective basis for measuring the effectiveness of therapy was lacking.

By 1975 it was evident that once patients had stabilized from the acute phase of a myocardial infarction, early ambulation might be beneficial (7). Immobilization beyond 5 days after recovery from the acute phase of an infarct

or its complications served no therapeutic purpose. Early hospital discharge after recovery was also found to be without adverse consequences. These findings were supported by a study of 522 patients consecutively admitted to a coronary care unit with the diagnosis of acute myocardial infarction (8). Prognostic stratification was best accomplished using the presence or absence of serious complications during the first 4 days of hospitalization to identify high- and low-risk groups. Patients with ventricular tachycardia or fibrillation, second- or third-degree A-V block, pulmonary edema or cardiogenic shock, persistent sinus tachycardia or hypotension, arterial flutter or fibrillation, and extension of infarction during the initial 4 days of hospitalization were found to be at greater risk of death during that hospitalization. On the other hand, the uncomplicated subgroup, which included 51 percent of the patients, had no inhospital mortality after surviving 4 days. It was concluded that this low-risk group of postinfarction patients might be safely discharged to home after 7 days.

The natural history of recovery from acute myocardial infarction has been of considerable interest. The success of treatment must be judged against the normal pace of recuperation without specific therapy. Improvement in the functional capacity of the cardiovascular system was found to occur in two phases--early and late (9). During the early phase of recovery, 3-6 weeks after infarction, myocardial oxygen supply/demand ratio becomes more favorable with a resultant rise in the threshold for ischemia. Later, at 3-6 months after infarction, cardiac stroke volume and output at rest and during exercise tend to increase. These changes occur in the natural course of recovery without a formal program of exercise. Improvement has been noted to be small but significant with considerable variation among patients (9). Change in exercise tolerance and functional work capacity among patients recovering from

uncomplicated myocardial infarction has been quantified and confirmed using periodic symptom-limited graded treadmill exercise testing (10,11). It has been suggested that persisting ischemia may be the most significant determinant of postinfarction functional capacity rather than the anatomic site of myocardial damage (11). The specific hemodynamic factors that contribute to improved functional capacity have been identified as an increase in maximal cardiac output and oxygen consumption, a lowering of heart rate at systolic submaximal work levels, and an increase in peak exercise heart rate (1).

Cardiac rehabilitation services are intended to identify patients at increased risk for further cardiac events as well as to restore their functional status. As a result, emphasis has been placed on the prognostic stratification of patients with coronary heart disease (12-14). Controversy has surrounded the predictive value of predischarge exercise testing contrasted to the merits of testing performed 3 or more weeks after an acute cardiac event. These considerations are of importance since the results of such tests are employed to select patients for early discharge, active rehabilitation, and the formulation of an exercise prescription. Various methods of combining historical and clinical patient characteristics have been proposed to guide preparation of patients for physical activity during convalescence and rehabilitation after discharge (12). This has caused the development of differing criteria for patient selection or exclusion from cardiac rehabilitation programs. Since the organization and content of programs have also been variable, comparison of outcomes is difficult. Generally, uncomplicated patients are tested for prognostically important exercise-induced variables such as angina, ST segment deviation, heart rate and blood pressure responses, functional capacity and arrhythmias (12).

Unfortunately, testing methods and end points have differed between studies as have the characteristics of selected patients. Treadmill and bicycle devices have been used to perform evaluations variously based on target heart rate, workload, or specific indicators of cardiac dysfunction. Pryor and associates reviewed the literature concerning early discharge of acute myocardial infarction patients and agreed that 50 percent of all cases could be safely sent home 7 days after admission (12). Those patients without evidence of significant ischemia or arrhythmia on an exercise test done before discharge, or up to 3 weeks after the event, could resume an active lifestyle within 4-6 weeks. The reproducibility of symptom-limited exercise test results in the 3 months after an uncomplicated myocardial infarction has been reported by Haskell and DeBusk (10).

A number of noncardiac disorders can affect the results of exercise testing and a patient's capacity to perform rehabilitative exercises (15). Disorders of ventilation, anemia, impaired tissue transfer of oxygen, peripheral vascular insufficiency, metabolic disease, medications, and orthopedic afflictions can influence the functional evaluation and rehabilitation of patients with coronary heart disease.

Cardiac rehabilitation is often divided into three phases (1,16). Phase I represents inpatient rehabilitation activities that begin 4-5 days after an uncomplicated infarction and extend until hospital discharge. Phase II is an ambulatory outpatient period that follows discharge and extends until the patient becomes sufficiently independent to perform prescribed exercise and carry out recommended long-term lifestyle changes. Phase III is a lifetime maintenance phase in which physical fitness and cardiac risk factor reduction are accomplished in an unsupervised (or minimally supervised) setting. Phase III is usually reached 3-6 months after infarction, CABG surgery, or other

commencement of Phase II.

Thus, cardiac rehabilitation is a process that begins with the diagnosis of coronary heart disease and continues indefinitely for the purpose of restoring and maintaining the patient to as normal a lifestyle as possible (17). The formulation and implementation of an exercise prescription is a significant part of cardiac rehabilitation services that has received the major share of professional attention. Educational activities and counseling to assist patient and family in assuming responsibility for adoption of health-promoting practices after a coronary event have long been accepted principles of traditional case management. The organization of comprehensive multidisciplinary cardiac rehabilitation programs may involve exercise groups of differing size with a diversity of patient monitoring practices. Classes or other teaching and counseling methods generally accompany the exercise program with varying degrees of individual attention for the patient. The specific approaches that are employed to achieve smoking cessation, weight reduction, dietary modification, or other behavioral changes are not generally described with scientific rigor in the literature of cardiac rehabilitation services. Peterson, Wenger, and others have emphasized the necessity for such lifestyle modification, but interprogram and intraprogram efficacy is not easily compared (17,18). Thus, improvement in functional capacity linked with a specific exercise prescription in the general context of a comprehensive rehabilitation program is most frequently presented. Long-term compliance with prescribed exercise and lifestyle change represents another area of concern, especially with respect to Phase III maintenance activities (19-22).

The components of cardiac rehabilitation services have generally included control of known cardiac risk factors for healthy populations (23). Most conditions that influence the initial development of coronary heart disease

exert their effect over protracted periods of time. The benefit of short-term risk factor reduction following an infarction or other cardiac event may be difficult to measure. May has noted that the principal question to be addressed is whether, after discharge from a hospital following an acute myocardial infarction, anything can be done to change the natural course of coronary heart disease by prolonging life (24). Others have emphasized the importance of enhancing the quality of life by reducing disability and the economic and social burdens of heart disease by means of cardiac rehabilitation (1). In the latter case, prolongation of life becomes one of many independent benefits (25).

The prescribing and management of exercise protocols for patients with coronary heart disease are based on an evaluation of exercise tolerance and cardiac abnormalities that may not be apparent at rest (15). Dynamic (isotonic) exercise, which involves changes in skeletal muscle length and joint movement, is generally the preferred modality for cardiac rehabilitation (26). However, static (isometric) exercise, characterized by little or no skeletal muscle shortening, also has its proponents. As a result, the mix of physical activities of a cardiac rehabilitation service may vary from program to program (1, 15, 26, 27). The relative merits of upper limb exertion as opposed to exercise of the lower limbs have been debated. But the total skeletal muscle mass involved may be the more important issue since heart rate and blood pressure responses to exertion are the effects being sought (26). In addition, it has been suggested that prolonged and vigorous exercise can result in adaptive cardiac changes that may improve left ventricular performance (16,28).

The exercise load prescribed for a patient is generally quantified in terms of heart rate limits, blood pressure, and measures of tissue oxygen

uptake in response to a particular level of chronic endurance activity (1,15,26,27,29). Age-predicted target heart rate has been used as a simple guide to physical conditioning exercises. However, the product of heart rate x systolic blood pressure, the "double-product," has been considered a more useful correlate of myocardial work and oxygen consumption or demand (15,25). Where heart rate is employed as a measure of exercise intensity, a common formula for determining maximal heart rate in normal individuals is 220 minus age (29). Submaximal exertion is often defined as an activity level producing a fraction (60-80%) of this maximal value. For this reason, the level of exercise that a patient achieves is often termed "symptom-limited," "submaximal," or "maximal."

Cardiovascular performance may be gauged by maximal oxygen uptake (26). This measure represents the body's ability to transport oxygen from the environment to working mucles during exhausting exercise. Although it is possible to monitor maximal oxygen uptake directly during controlled exercise, it is technically quite difficult. As a result, proxies such as the double product or the "MET" (metabolic equivalent) are frequently employed. One MET equals the constant rate of oxygen uptake of a person seated at rest, or 3.5 mL/kg/min (30). In this way, the oxygen cost and cardiac work required to accomplish a known level of exertion can be calculated. An average 40-year-old male has been estimated to function at 10 METs at maximum capacity (31). To a lesser extent, other energy measurements such as bicycle ergometry or treadmill staging criteria are used to quantify the functional work capacity and state of physical conditioning in patients with coronary heart disease. Maximal oxygen uptake during exercise responds to variations in oxygen transport as well as the ability of muscle to extract oxygen from blood. For this reason, either increased pumping efficiency brought about by an

improvement in myocardial status or an increase in oxygen uptake by peripheral tissues can result in improved functional work capacity. In either case, the body may achieve higher levels of exertion without exceeding the myocardial threshold for angina. Cardiac rehabilitation services are designed to promote a level of physical fitness among enrollees that permits normal daily activities to be sustained without angina or other adverse consequences. This "training effect," when attained, is hypothesized to allow greater exercise endurance per volume of blood pumped before the myocardial threshold for ischemic symtoms is reached (1,15,27,30).

Phase II postdischarge cardiac rehabilitation programs are usually conducted with on-site medical direction. However, exercise sessions may be under the immediate supervision of a nurse, physical therapist, exercise physiologist, physical trainer, or physician. Both DeBusk and others and Stevens and others have reported satisfactory results with unsupervised medically prescribed exercise regimens performed by postinfarction and post-CABG surgery patients in their homes (32,33). Careful selection of low-risk cases is emphasized by these authors. Erb, and others have recommended that a physician be in charge of the rehabilitation program and should be present during therapeutic exercise sessions (31).

Electrocardiographic monitoring of patients performing prescribed exercises is a routine feature of some cardiac rehabilitation services (1, 15, 34-36). Either hard-wired or telemetric equipment may be used. The recommended frequency of monitoring during exercise runs the gamut, from occasional to continuous. Transtelephonic monitoring for patients exercising at home has also been used. Participants in community-based maintenance programs may not be routinely monitored during group sessions (37). Since the cardiac status of patients admitted to rehabilitation services is quite

variable, cardiographic monitoring practices differ markedly from program to program. Exercise prescriptions may also differ in the level of exertion to be achieved by the patient. This becomes an additional factor in selecting the form of monitoring that assures an acceptable level of safety.

The duration of Phase II postdischarge cardiac rehabilitation programs is generally keyed to the time necessary for therapeutic physical reconditioning (31). However, specific target goals and end points set for the patient are often based on empirical clinical impressions. Erb and others have suggested that a peak functional capacity of 8 METs meets the demands of most occupations (31). Up to 6 months is given as the usual time devoted to supervised exercise therapy. Discharge from the program depends on a medical judgment based on resting and exercise ECG, blood pressure response to exertion, and symptoms.

Peterson proposed a "conditioning index" representing the ratio between the double product (cardiac work) and prescribed ergometer workload (external work) as a means of determining the maximal endpoint for physical training (15). In practice, external work is gradually increased until the double product reaches a plateau at which there is no further drop in its value in response to exercise load.

Wenger and others, Peterson, and Erb and others estimate that a program of prescribed, supervised exercise for patients with coronary heart disease customarily requires at least three sessions per week for 3-6 months (1,15,31). Upon reaching a satisfactory clinical end point, the patient is discharged to an unsupervised Phase III regimen to be followed at home.

Wenger and others note that "the exercise prescription, varies with the needs and goals of each patient, age and general health status, current exercise capacity, musculoskeletal competence, prior exercise activity and

level of training, planned occupational and recreational activities, and the patient's skills, likes and dislikes as well as accessibility of exercise equipment" (1). The duration of each session involves about 1 hour for exercise plus the time required for educational and consultative activities.

Costs

Kannel and Thom have estimated the treatment costs of coronary heart disease at $8.6 billion annually (3). This disease is responsible for mortality and disability during a person's most productive years. In 1984, Staniloff analyzed the costs of cardiac rehabilitation services (38). He found that on-site medical supervision was considered desirable for safety, but might not be required for lower-risk patients. The nature of medical supervision provided was noted to be the major determinant of a program's cost. It also tended to restrict access since program location may be linked to the availability of physicians. Staniloff identified the goal of on-site medical supervision as the avoidance of situations requiring defibrillation. He estimated the cost per patient session for medically supervised EKG monitored programs to range between $20-70. The cost with a physician but without EKG monitoring was $4-14 per patient session. A lower patient-to-supervisor ratio in EKG-monitored programs was found. Various attempts have been made to adjust professional supervision in accord with severity of illness criteria. Home-based programs, community programs without a full-time physician, and medically structured services of graded complexity and sophistication will obviously vary in cost. Thus, cost tends to be related to the perceived margin of safety attributed to more intensive supervision of the patient, rather than to programmatic content *per se*.

RATIONALE

Cardiac rehabilitation services are designed for the secondary prevention of physical and social disability due to coronary heart disease. Their development has followed the changing attitudes of cardiologists with respect to early mobilization and resumption of customary activities after myocardial infarction or other cardiac events (38).

Rehabilitation presents itself as a multidimensional problem (24). Exercise therapy is prescribed to improve cardiovascular functioning as well as to increase survival. Cardiac risk factor reduction is undertaken to reverse or retard the progression of atherosclerotic lesions. Behavioral and educational techniques are used to improve psychological and social functioning leading to a better adaptation to heart disease by the patient and family. Medical management of the patient's clinical status accompanies these less traditional activities. Progress of cardiovascular functional status is routinely evaluated by periodic exercise stress testing. Improvement has been attributed to the more efficient functioning of peripheral muscles as well as a possible direct beneficial effect on the myocardium. Exercise-induced stimulation of collateral coronary artery circulation has also been hypothesized. Continued compliance with the prescribed cardiac rehabilitation regimen is required to maintain its benefits.

REVIEW OF AVAILABLE INFORMATION

The relationship between physical exercise and cardiovascular health has been of long-standing interest. Simply stated by Littell, "exercise can be sustained only if there is increased blood flow to those tissues with

increased metabolic needs" (39). In the normal individual, physical exercise can augment cardiac output up to sixfold over average resting levels. This is accomplished by an acceleration of heart rate accompanied by an increase in stroke volume. Heart rate normally rises linearly with exercise intensity until a plateau is reached, representing the maximum level for the individual being observed. Littell notes that this forms the basis for using heart rate as an index for exercise stress during exercise testing (39). On the other hand, stroke volume does not increase linearly with physical exertion. A disproportionately rapid rise tends to occur initially at low levels of exercise intensity. Thus, increased stroke volume principally accounts for increasing cardiac output until about 30-40 percent of maximum exercise intensity has been reached. At that point, further augmentation of output is attributable to increased heart rate. Rising aortic pressure usually accompanies increased cardiac output during exercise, which obliges the heart to pump a greater volume of blood against higher arterial pressure per unit time. Thus, the force of myocardial contraction must increase to maintain stroke volume output. Littell concluded that any compromise of these factors will impair the heart's ability to support exercise (39). Further, cardiac output must be matched by venous return of blood to the heart; a process that is normally facilitated by working skeletal muscles.

The peripheral circulatory adaptations that occur with exercise training involve a shift in blood flow due to selective arterial dilation and constriction. Working skeletal muscle experiences increased flow while compensatory vasoconstriction of splanchnic, renal, and nonworking muscle tissue takes place (39). Once circulatory equilibrium has taken place during sustained exercise, both heart rate and systolic blood pressure will have increased in proportion to the intensity of exertion until a plateau has been

reached that represents a person's maximum exercise capacity. The level of work intensity can be expressed in units of energy (ergs, watt-hours, kilopon-meters/minute) or as a percentage of the maximum work capacity that an individual can attain.

Littell attributed the regulation of cardiovascular responses to exercise to a combination of neural and muscular factors (40). Centrally mediated neural control largely influences cardiac activity and distribution of blood flow to nonstressed tissues, while local metabolic autoregulatory signals determine flow to exercising skeletal muscles. In addition to increased blood flow, exercise can also facilitate the ability of muscle to extract oxygen from hemoglobin (39). To the extent that physical training can improve blood flow and the efficiency of oxygen extraction by skeletal muscle, then equivalent work capacity may be reached at lower levels of cardiac activity. If cardiac muscle can be made to function more efficiently by means of a similar training effect, then it too may achieve greater functional capacity with improved efficiency. Sonnenblick and others characterized the realization that cardiac muscle is subject to similar physiologic factors and principles as skeletal muscle as a major advance in our understanding of myocardial oxygen consumption (41). A close relationship was noted between the product of peak ventricular pressure and heart rate to myocardial oxygen consumption. The velocity of myocardial fiber shortening, or contractile state, may also influence oxygen consumption. It was concluded that anginal episodes are a function of myocardial oxygen consumption and that their occurrence could be reduced by interventions such as beta-blockers that effectively modify cardiac tension per minute and contractile state. For this reason, the "triple product" of systolic pressure, heart rate, and ejection time has been used as an additional index of myocardial activity.

In 1972 Redwood and others reported favorable results in seven patients with angina after they received 6 weeks of intensive physical training (42). Radiographic evidence of coronary artery disease was present in all cases. Bicycle ergometry was performed pretraining, at 3 weeks, and after 6 weeks when training was concluded. The patients exercised upright on bicycle ergometers twice daily, 5 days a week, with an increasing load each session until angina occurred. Electrocardiographic monitoring accompanied all exercise sessions. Six patients completed the 6-week training course; the seventh dropped out at 3 weeks because of a noncardiac medical problem. Progressive improvement in exercise capacity was reported throughout training. A significantly longer duration of exertion was required to induce angina after physical conditioning. An increase in maximal total body oxygen consumption occurred in all patients. The post-training, triple product responses of each subject were compared with the values that represented the pretraining level of exercise required to induce angina. Four patients had a significant increase in triple product, three did not show a significant change. Redwood and others concluded that a "rapid, progressive and maintained improvement in exercise capacity can be induced by relatively brief periods of physical training." The myocardial oxygen costs of a given exercise load were found to be reduced. Thus, a higher post-training workload and total body oxygen consumption were achieved before angina was precipitated. Whether this improvement was attributable to an improved circulatory response to exertion, enhanced myocardial function, or to an altered threshold for ischemic pain could not be determined. The study did not employ a control group. No adverse effects due to exercise were reported.

Physical deconditioning due to protracted bedrest has been considered a contributing factor to disability in patients recovering from myocardial infarction. DeBusk and his associates studied the effects of exercise conditioning in 12 healthy middle-aged men after they had been subjected to 10 days of bedrest (43). A study group of six men performed prescribed physical exercise for 60 days after bedrest while six controls resumed their customary daily activities. Heart rate at a submaximal workload decreased and peak oxygen consumption increased significantly in the exercise group after 60 days compared with controls. However, DeBusk found that "simple resumption of usual physical activities after bedrest was as effective as formal exercise conditioning in restoring functional capacity to before-bedrest levels." Peak oxygen consumption was restored to pretest levels in both groups at 30 days. This restoration of functional capacity after bedrest was attributed more to the orthostatic stress of usual physical activities than to the performance of formal exercise. The importance of orthostatic stress in overcoming the effects of bedrest in patients recovering from myocardial infarction has also been noted by Franklin (30). Orthostatically induced cardiac underfilling during convalescence in a hospital bed was felt to cause a diminution in aerobic capacity exclusive of myocardial damage.

Sivarajan and coworkers studied the effects of early predischarge exercise training among 258 hospitalized patients recovering from acute myocardial infarction (44). Evaluation was accomplished by treadmill testing 1 day before discharge. Patients were included in the study within 7 days of hospital admission and all had been free of cardiac complications for at least 24 hours. Cases were randomly assigned to a control group or one of two exercise groups. One study group received an exercise intervention only and another received exercise, teaching, and counseling. Exercise was prescribed

individually and did not exceed 3 METs. The authors were unable to discern any beneficial or adverse effects of early formal exercise after hospitalization for acute myocardial infarction. Similar proportions of patients in each group were receiving beta-blockers, however, no impediment to physical conditioning was noted in these individuals. A possible psychological benefit was identified since patients starting an exercise program while hospitalized might be motivated to lead a less sedentary existence after discharge.

In 1975, Wilhelmsen and coworkers reported on a long-term randomized controlled trial of physical training after myocardial infarction (45). The control group was composed of 142 men and 15 women, and the training group had 138 men and 20 women. All were discharged alive from the hospital after an acute infarction between 1968 and 1970. Follow-up examinations were conducted at 3 months, and at 1-, 2-, and 5-year postdischarge intervals. Both controls and study patients were treated at a special heart clinic; however, the study group was given three half-hour physical training sessions each week that were supervised by a physician and physiotherapist. Not all patients continued exercising at the clinic, some followed an independent home regimen. Training was begun 3 months after hospital discharge. Exercise intensity was limited to 80 percent of maximal heart rate or the point at which angina occurred. Ultimately, 112 patients commenced the physical training program: 105 in the supervised clinic and 7 independently. Exclusions were based on exercise testing and cardiac status. After 1 year, a majority of patients in the experimental group had ceased training. Dropouts accounted for 61 percent and 79 percent of the clinic and home training groups, respectively, with further declines over the next 3 years. A significant favorable effect of physical training on mortality or reinfarction could not be demonstrated. Patients who

continued training were found to improve their physical working capacity to the same extent as healthy individuals. Prognosis for up to 2 years was reported to depend largely on a history of prior myocardial infarction, size of infarct, and smoking habits. The authors concluded that the value of a physical training program was principally connected to the quality of life rather than to longevity.

Tirlapur and others published an account of cardiac rehabilitation in 56 select patients admitted to a cardiac care unit with a first myocardial infarction who were 33 through 58 years old (46). Physical exercise began on the second day of admission and continued for 6 weeks after discharge. Training was conducted at home under the once-a-week supervision of a remedial gymnast. Patients were excluded from the program if they had persistent hypotension, heart failure, cardiac arrhythmia, heart-block, residual angina, diabetes requiring insulin, or significant joint disease. Prescribed exercises were progressively more strenuous, increasing in duration from 30-60 minutes in the course of the program. It was found that 77 percent of the patients had returned to work at an average of 9.5 weeks postinfarction; 61 percent to their original jobs and 16 percent to lighter work. During rehabilitation one patient died and five more were readmitted to coronary care, three with confirmed reinfarctions. No significant differences were measurable in the resting and exercise heart rate and double product indices of the group between week 1 and week 6. The author concluded that when a patient can complete 60 minutes of "strenuous" exercise, he can be considered for return to work. This study was uncontrolled and the usual occupations of the subjects were not specified. Details of physical exercises and other aspects of the rehabilitation program were not given.

In 1979, Kallio and colleagues presented the results of a randomized multifactorial cardiac rehabilitation trial conducted in cooperation with the World Health Organization (47). Three hundred seventy-five patients consecutively admitted from 24 medical centers with acute myocardial infarction were randomly assigned to either an organized rehabilitation program or to their own physicians and clinics. The intervention consisted of a prescribed, supervised physical exercise program, frequent medical examinations, anti-smoking and dietary advice, and psychosocial counseling. Rehabilitation started two weeks after hospital discharge and was followed for 3 years. It was found that cumulative coronary mortality was significantly lower in the study group principally resulting from a reduction in sudden deaths. The greatest decline in mortality occurred in the 6 months following an acute myocardial infarction. Overall 3-year mortality was 18.6 percent in the intervention group as contrasted to 29.4 percent among controls (p=0.02). Reinfarction rates however, were 18.1 percent in the study patients and 11.2 percent in controls--not a statistically significant difference (p=0.10). The authors concluded that their total multifactorial cardiac rehabilitation program resulted in a significant reduction of sudden deaths that was attributable largely to "organized aftercare during the first six months after an AMI." The educational, medical, and exercise components of the program were not evaluated independently. No patients were excluded from the study by reason of their physical or medical condition. A smoking cessation rate of about 50 percent in both groups occurred largely during the initial period of hospitalization. Systolic and diastolic blood pressures were significantly lower in the study patients as were slightly lower levels of serum cholesterol, triglyceride, and body weight at each of their three annual evaluation examinations.

Kavanagh and others conducted a study of risk factors predisposing to recurrent infarction among 610 male patients between 40 and 58 years old in an exercise-centered rehabilitation program (48). The subjects were selected and enrolled an average of 8 months after infarction and participated an average of 3 years each. Over the period of the study 23 patients had a fatal recurrence, and 21 patients had a nonfatal recurrence of infarction. The exercise program consisted of a progression from long-distance walking to jogging as permitted by each person's clinical condition. Exercise was individually prescribed in terms of the daily distance to be covered in a specified time. Patients were requested to make weekly visits to the rehabilitation center for 2 years with a change to one visit every 8 weeks thereafter. Clinical and laboratory tests of risk factors were performed at 6-month intervals. Body weight, blood pressure, estimated oxygen intake, cardiogram, and serum cholesterol of each patient were followed. Exercise was to be performed five times weekly, but compliance was variable. About 83 percent (505 patients) of the group fulfilled their activity prescription at least three times each week. Only 27 patients abandoned their exercises completely while about 14 percent were exercising at least twice weekly. The average period of exercise for the 27 dropouts was 14 months, with a range from 3-34 months. Analysis of results was based on a comparison between three groupings of ptients: a fatality group, a nonfatal reinfarction group, and a control group composed of all other patients. It was found that noncompliance with exercise prescriptions was the most useful individual index of a poor prognosis. Other adverse factors were identified as angina at the final exercise test, cardiac enlargement, certain cardiographic S-T abnormalities, serum cholesterol greater than 270 mg/100, persistance of cigarette smoking, and use of digitalis or diuretic agents. Differences in training responses

among the three groups were not significant. It was not possible to find a causative relationship between lack of exercise and an adverse outcome. No difference was noted between the age of patients who died and the remainder of the subjects. However, Kavanagh's group concluded that the prognosis for postinfarction patients who exercised and had such risk factors as S-T depression on exercise, elevated serum cholesterol, and continued cigarette smoking, was at least as good as that for patients without these risk factors who did not exercise.

DeBusk and associates compared the cardiovascular effects of exercise training among uncomplicated postinfarction patients with the results of a medically supervised gymnasium program (49). Seventy men under 70 years old were assigned either to a home exercise, gymnasium exercise, or a no exercise control group. Stratification based on electrocardiographic S-T segment depression 3 weeks after infarction was performed. Patients without ischemic S-T depression were allocated to all three groups, whereas those with S-T depression or exercise-induced angina were only allocated to the gymnasium or no-exercise groups. Prescribed physical exercise was performed by the patients in the two study groups based on symptom-limited exercise testing done three weeks after an acute infarction. Testing was repeated for comparison purposes 4 and 8 weeks later. A few patients took nitrites or propanolol during the study, but none received digitalis. No attempt was made to change their diet, body weight, or smoking habits. Although 89 patients were originally included, there were 19 exclusions or dropouts because of clinical contraindications revealed by treadmill testing (five cases), inability to attend gymnasium training (six cases), and eight who withdrew in the course of the training period 3-11 weeks after infarction due to medical complications (six cases) or nonmedical reasons (two cases). Patients

assigned to gymnasium training exercised for one hour three times per week for 8 weeks. Patients in the home group were instructed to perform 30 minutes of stationary bicycle exercise daily. A range of training heart rate was established for each patient based on 70-85 percent of the peak rate achieved on initial testing with a revision after repeat testing 4 weeks later. Peak functional capacity expressed in METs was the limit employed to compare the performance of the three groups. All groups showed improvement at 11 weeks. Statistically significant results were reported for members of the gymnasium group without exercise-induced ischemic S-T depression or angina when compared to the performance of the no exercise group. Thus, an increase in functional capacity as well as such training effects as a decrease in heart rate and systolic blood pressure at submaximal workload was reported for all patients during the 8-week study period. It was speculated that the process of exercise testing itself might have encouraged the notraining group to engage in more active lifestyles than individuals not afforded the assurance of this intervention. Overall, the patients found to benefit most from exercise training were the group at least risk from physical activity, that is, the patients without ischemic abnormalities during treadmill testing undergoing supervised training. The authors concluded that symptom-limited treadmill testing was of value in providing guidelines for postinfarction physical activity and that functional capacity commonly increases to near-normal levels during the 8 weeks after an uncomplicated infarction even if no formal exercise is prescribed. In patients receiving formal exercise training, the greatest improvement in functional capacity occurs in those without ischemic electrocardiographic abnormalities. It was further concluded that this latter group might safely achieve similar results performing low-level home exercises.

DeBusk and associates and Miller and associates reported the results of further research on home rehabilitation in 1984 and 1985 (32,50). The investigators continued their reliance on exercise testing performed alone or with other techniques to identify a low-risk subset of postinfarction patients deemed amenable for medically directed rehabilitation at home or in a group clinic. One hundred twenty-seven men in their fourth and fifth decade recovering from an uncomplicated myocardial infarction were again randomly assigned to an at-home or group rehabilitation protocol after symptom-limited exercise testing 3 weeks after the coronary event. Controls were employed in one of these studies (50). They were either tested at 3 weeks and given no prescribed exercise, or treadmill tested at 26 weeks after no training. Functional capacity was significantly better in the two groups given physical exercise training when compared to the controls. Furthermore, there was no difference in functional improvement found between the patients who trained at home and the rehabilitation clinic subsets. No significant difference was detected in the incidence of adverse cardiac events among the four groups studied. Between entry into the program at 3 weeks after infarction, and completion at 26 weeks', adverse events affected from 11 percent to 19 percent of the subjects. The highest rate occurred in the control group who did not receive a 3-week exercise test. The home training patients used portable heart rate monitors during exercise and their electrocardiographs were telephonically monitored twice weekly by a clinic nurse. Group clinic training was carried out under the supervision of a physician and two nurses for 30-35 patients per session. No direct, training-related, adverse cardiac events were noted. The authors concluded that 47 percent (280,000) of

Americans who annually survive a myocardial infarction "may be capable of safely completing 3 months of home training--nearly five times the number of postinfarction patients currently undergoing group--training" (50).

Froelicher and colleagues published a series of reports between 1980-1984 concerning changes in ventricular function during exercise among cardiac rehabilitation patients (51,54). Their initial uncontrolled studies involved small numbers of patients who underwent stress thallium and radionuclide ejection fraction studies before and after 6-months of an exercise rehabilitation program (51-53). Preliminary results indicated that improvement in myocardial perfusion and function may occur as a result of exercise training in addition to peripheral noncardiac changes that contribute to increased functional capacity. Froelicher and others reported the results of a randomized controlled study of these phenomena in 1984 (54). Male volunteers between 35 and 65 years of age with stable coronary heart disesase were solicited for this study. Patients with complications such as congestive heart failure, unstable dysrhythmias, diabetes, pulmonary disease, hypertension, claudication, or orthopedic problems were excluded. The subjects were divided into two groups, an exercise program group and controls assigned to a "usual care program." Exercise tests were performed at the onset and at the termination of the study 1 year later. The participants had either a history of myocardial infarction, stable exertional angina pectoris, or coronary artery bypass surgery. All were at least 4 months past a significant cardiac event or surgery. Exercise tests were symptom- or sign-limited maximal efforts. The group assigned to exercise training were started in a monitored class for the first 8 weeks. Intensity was initially set at 60 percent of estimated maximal oxygen uptake and increased gradually to 85 percent where possible. Upon safe completion of 8 weeks with monitoring, the

patients progressed to a gymnasium or walk-run program. The control group was offered a low-intensity walking program. No episodes of cardiac arrest or other major complications occurred during exercise sessions. There were five medical dropouts among the controls and six from the exercise group in the 12-month course of the study. Several additional members of the exercise group dropped out for nonmedical reasons. Repeat testing at 1 year was ultimately carried out on 69 of 74 original controls and 59 of 72 patients in the intervention group. A significant training effect was found in the members of the exercise group as evidenced by a decrease in resting and submaximal heart rate, and an increase in measured and submaximal oxygen uptake. As a group, the intervention patients exhibited a significant improvement in thallium images; however, this difference was not sustained when scoring was done individually using paired, before and after studies of the same patient. End-systolic volume showed a significantly lower percentage change among intervention patients when compared with controls The authors concluded that a "modest" improvement in myocardial perfusion and function had been demonstrated among the patients who received 12 months of prescribed exercise training in addition to a training effect that was attributable to peripheral muscular adaptation.

A similar uncontrolled study of ventricular function after exercise training was conducted by Cobb and others (55). Fifteen patients younger than 65 years who were between 6 weeks and 6 months postinfarction were involved. Maximal treadmill exercise testing and radionuclide angiography at rest and exercise were employed to evaluate the patients before and after a 6-month training period. Eleven patients completed the protocol. Two dropped out for nonmedical reasons, and two more experienced cardiac complications. The subjects were given 6 months of exercise training, three times a week, at an

intensity of 75-85 percent of maximal heart rate achieved during the initial treadmill test. A significant training effect was found in all patients who completed the protocol. They also experienced a significant reduction in body weight and serum cholesterol levels. Left ventricular function did not change significantly with exercise training. It was concluded that exercise capacity was improved primarily by peripheral effects, not ventricular adaptation. The authors noted that all their patients were within 6 months of an infarction. This represents an important difference from the work of Jensen and Froelicher since many of their patients experienced a cardiac event more than 6 months prior to the study (51-54). In an earlier study of 46 men, mean age 54 years, Savin and associates had determined that a significant improvement in aerobic exercise capacity normally occurs between 3-11 weeks after infarction without formal exercise training (11). They reported an average 25 percent increase in directly measured maximal oxygen uptake with comparable improvements in peak heart rate and double product during the 3- to 11- week postinfarction interval under study.

In 1981 Shaw reported the results of a 3-year, multicenter trial of prescribed supervised exercise in 651 men with myocardial infarction (56). The patients were aged 30-64 years and were 2-36 months' postinfarction. Randomization between an exercise and control group was accomplished. The 328 men of the intervention set received an exercise prescription based on 85 percent of peak heart rate achieved on a treadmill exercise test at entry. For an initial 8 weeks, the participants performed 1 hour of supervised electrocardiographically monitored exercise 3 days each week. Thereafter the study patients attended three supervised sessions weekly in a gymnasium without monitoring for the balance of the 3-year period. The intervention group was examined and exercise tested at randomization 9 weeks later, and

each 6 months for the duration of the project. Although over 900 patients were originally referred for enrollment in the trial, about one-third were excluded based on a 6-week prerandomized low-level exercise program intended to identify "likely nonadherers" to the planned protocol. Stratification of the groups into a number of categories was performed. Behavioral, physiologic, and socioeconomic characteristics were considered for this purpose. Shaw found "no suggestion of benefit from the exercise program with relation to cardiovascular morbidity." Mortality reduction as a result of exercise training was considered a possibility, "but the evidence is not convincing" in the opinion of Shaw. The total mortality rate in the intervention group was markedly less than might normally be predicted; however, no significant difference between subjects and controls was found. This was taken to indicate that patients selected for participation in exercise rehabilitation programs may be at considerably lower risk than the general population of patients with coronary heart disease. For this reason the author expressed a caveat in accepting the results of uncontrolled clinical trials of exercise training.

Mayou and others studied early rehabilitation after myocardial infarction in 129 men under age 60 (57). The patients were randomly assigned to either a control group or one of two intervention groups: "exercise training" and "extra advice." The period of study began with hospital admission for acute infarction and extended for 12 weeks thereafter. Both groups received standard medical care and the exercise group attended eight sessions of twice-weekly exercise that started within 4 weeks of the infarct. Members of the advice group and their wives were given three or four counseling sessions with a "therapist." Details of the advice protocol were not given, nor was the professional training of the therapist. After 12 weeks, and again at 18

months, the patients were evaluated by exercise and psychosocial testing. No complications from stress testing or exercise training were encountered. It was found that overall "rehabilitation was of little benefit to cardiac function, everyday life, or emotional state." However, at 12 weeks the exercise patients achieved higher levels of work capacity and were found to be more satisfied with their treatment.

Raineri and associates studied the effects of a 2-year cardiac rehabilitation program carried out by 71 male postinfarction patients selected from 225 consecutive admissions for acute myocardial infarction (58). Exclusions were based on age over 65 years as well as unspecified medical grounds or refusal to participate. Preparatory evaluation was performed 3 weeks after clinical stabilization. Bicycle ergometry was used to measure physical capacity. Thirty-eight patients underwent echocardiographic examinations to assess anatomic variations, and left ventricular performance was measured by a nonimaging nuclear probe. A control group of 35 patients excluded by reason of travel distance from the clinic site were used for comparison with the 71 patients who received prescribed exercise training.

In 1982 Cann and others investigated the possibility that short-term exercise leading to physical training effects might benefit patients with severely impaired left ventricular function (59). Ten patients with documented infarction and a radionuclide study that demonstrated left ventricular ejection fraction of less than 27 percent were retrospectively selected from the register of cardiac rehabilitation participants at Duke University. These cases represented the lowest 15 percent of ejection results in 722 survivors of infarctions who received cardiac catheterization and ventriculography between 1977-1979. Ages ranged from 44-71 years. All 10 patients participated in a medically supervised exercise program for at least

2 months. Three subjects then continued exercising at home while the remaining seven stayed under medical supervision. Followup spanned a range of 4-37 months with a mean of 12.7 months. Treadmill studies were performed every 3-6 months to monitor training effects. Exercise was prescribed based on a percentage of maximal heart rate for three to five sessions per week and no adverse cardiovascular events occurred. Two patients died during the program from causes unrelated to exercise. A significant training effect due to physical conditioning was identified among all but one of the patients. The author considered these results to be preliminary, however the feasibility of cardiac rehabilita- tion in patients with severe left ventricular dysfunction was suggested.

A randomized controlled study of an exercise program, started about 4.5 days after acute myocardial infarction, was reported by Sivarajan and associates (60). Selected were 258 patients from a pool of 1,418 with documented infarctions. Exclusions were variously based on cardiac and noncardiac medical complications, age over 70 years, from the rehabilitation facility, physicians refusal, and other criteria. There were 88 patients allocated to an exercise group, 86 to an exercise and teaching-counseling group, with 84 patients assigned to a control group. Exercise content which was identical for the two intervention groups consisted of a calisthenics and walking program requiring about 2-3 METs during their hospitalization, followed by a progressively more strenous regimen for 3 months after discharge. Patients had their exercises prescribed at weekly, 30-minute clinic sessions and were instructed to exercise twice daily at home while monitoring themselves for adverse symptoms. The exercise and teaching-counseling group was given eight, 1-hour sessions emphasizing risk factor reduction and psychosocial adjustment to infarction that coincided with clinic

exercise visits. Patients in the control group received conventional medical and nursing care. Evaluation was made on discharge from the hospital and at the 3-month clinic visits. A symptom-limited treadmill test was also performed at 3 and 6 months. The authors found no evidence of clinical or physiologic benefits or any deleterious effects attributable to formula low-intensity exercises performed after myocardial infarction. Routine medical care was considered equally effective in permitting spontaneous convalescence. The teaching-counseling intervention significantly improved patients' knowledge about their medications, but physiologic benefits were not apparent. A decrease in resting heart rate as well as increased systolic and diastolic blood pressure at rest and with submaximal exercise were noted in the overall group at 3 months without further improvement at the 6-month interval. It was concluded that the costs of structured, formal exercise programs were difficult to justify. However, the exercise regimens employed in the study were individual and largely unsupervised.

Ott and others applied the sickness impact profile (SIP) to the same three groups of patients studied above in an independent effort to measure subjective psychological and social effects of the teaching-counseling intervention (61). A statistically significant psychosocial improvement was noted in the teaching-counseling group when compared with results among the controls or the exercise-only subsets. Social interaction, alertness,communication, and emotional behavior are the categories subsumed within this portion of the SIP. Social interaction was the area from which the significant difference between groups had stemmed.

The Ontario Exercise-Heart Collaborative Study was designed to assess the protective effects of high intensity exercise among patients with a history of myocardial infarction (62). Its objective was to test the hypothesis that a

50-percent reduction in the recurrence of infarction could be attained over a 4-year period. Rechnitzer and colleagues randomly allocated 733 men with documented infarctions to high-intensity or low-intensity exercise groups. The subjects ranged in age from 25-55 years (median 47.5 years) and time since last infarct was from 2-17 months (median 6.2 months). The two groups were stratified by presence or absence of hypertension, angina, or type A behavior patterns, and blue collar or white collar employment. Baseline measurements included height, weight, skinfold thickness, electrocardiography, hemoglobin, fasting plasma glucose, cholesterol, and triglyceride levels. Bicycle ergometry was carried out initially at 6 months, and each 12 months thereafter. The high intensity exercise group underwent endurance training based on each patient's graded exercise test results. Walking or jogging was prescribed to a level of 65-85 percent of estimated maximal oxygen uptake. This group participated in one to two supervised sessions weekly for 8 weeks, which were then supplemented by four times per week unsupervised exercise. The low intensity exercise group met weekly for "relaxation and supervised recreational activities--structured to produce minimal training." Supervised sessions for both groups lasted 1 hour. A physician was present at all supervised sessions. Overall reinfarction rates, fatal as well as nonfatal, were 14.2 and 13.0 percent for the high- and low-intensity groups. A significant reduction in heart rate was found in the high-intensity group, which attested to a difference in training effect between the two groups. The authors concluded that high-intensity exercise training did not provide an advantage for the subjects assigned to that group. They suggested that low intensity exercise together with group social support have a beneficial effect that is equivalent to "an aggressive exercise prescription centered around jogging."

Roman and his group in Chile performed a controlled study of rehabilitation in 193 patients recovering from a first acute transmural myocardial infarction (63). One hundred patients served as controls while 93 persons performed prescribed, supervised exercise for 30 minutes three times each week. Training intensity was based on 70 percent of maximal heart rate achieved by bicycle ergometry at the beginning of the trial. The supervised exercise program lasted an average of 42 months (range 6-108 months), while followup averaged about 56 months. Patients were under age 70 years and free of complications such as severe arrythmias, marked left ventricular enlargement or aneurysm, persistent cardiac failure, severe diastolic hypertension, and postmyocardial infarction angina. Baseline ergometry was performed 2 months after the acute attack. Control and rehabilitation groups were considered comparable with respect to both demographic and medical characteristics that might alter prognosis. Eighteen patients dropped out of each group in the entire 9-year course of the investigation. The authors found that cardiac rehabilitation significantly reduced the long-term frequency of angina. However, the incidence of mortality, recurrent infarctions, severe arrythmias, and cerebrovascular strokes did not differ significantly between the control and intervention groups. A significant mean rise in both maximal oxygen consumption and physical work capacity was noted in the rehabilitation group and in 90 percent of these patients taken individually. This was viewed as a net beneficial outcome. A significant decline in smoking, hyperlipidemia, and sedentary lifestyle also occurred among the cardiac rehabilitation patients.

The effects of 3 months' physical training on intrinsic cardiac function after acute infarction were studied by Barletta and others (64). Twenty-seven patients consecutively admitted to a cardiac rehabilitation program in

Florence, Italy 4 weeks following myocardial infarction were involved. Three groups were formed based on ST-T changes during a maximal ergometric stress test: patients without ST-T changes; those with over 1 mm depression in one or several leads; and third, those with ST-T elevation of 2 mm. Contraindications for rehabilitation were unstable angina, congestive heart failure, and coexisting medical conditions. The exercise program consisted of medically supervised calisthenics with bicycle training three times weekly. Intensity was set at 70-85 percent of heart rate achieved at the initial stress test. Group counseling sessions were also conducted, but details were not provided in the report. Radionuclide angiography at rest and during exercise was performed before and after the 8-month rehabilitation training course. It was found that all patients increased their work capacity and had a decrease in double product at the completion of training. Significant increases in left ventricular ejection fraction and in contractile regional performance at rest were also noted. Some variations in results occurred between the three groups of patients. It was concluded that the effects of rehabilitation were related to the site of infarction and the functional status of the ventricles. In the absence of a control group, the authors acknowledged that improved performance after the rehabilitation program "could be part of the natural history of the disease."

In the Netherlands, Vermeulen and others conducted a prospective randomized trial to test the effect of cardiac rehabilitation on morbidity and mortality (65). Ninety-eight male patients aged 40-65 years were randomly distributed to a rehabilitation or control group 4-6 weeks after hospital discharge for a first acute myocardial infarction. Baseline maximal symptom-limited stress testing was done and the intervention group commenced a 6- to 8-week multifactorial rehabilitation program. Physical, social, and

psychological elements were included. Both groups received similar medical treatment in all other respects. It was found that the incidence of progressive coronary artery disease as evidenced by the development of angina, and reinfarction was significantly greater among the controls after 5 years of followup. There were seven deaths in the same period without a significant difference in mortality between groups. The authors reported that "the apparent effectiveness of the rehabilitation program was confined to these patients with elevated serum cholesterol and/or who smoked more than 19 cigarettes/day before the first myocardial infarction." However, no change in smoking habits or body weight was attributable to the rehabilitation program. Survivors of the study group showed a significant decline in serum cholesterol when compared with surviving controls after 5 years. Overall, both morbidity and the combination of morbidity and mortality were 50 percent lower in the rehabilitation group. The researchers concluded that these beneficial outcomes were due to a direct effect on myocardial perfusion and the reduction in cholesterol levels. Details of exercise and educational interventions were not presented.

Stern and others have studied the effects of group counseling compared with exercise therapy after myocardial infarction (66). Their 106 subjects were between 30 and 69 years old, of both sexes, and had an infarction between 6 weeks and 1ne year prior to the study. Selection was based on a mean treadmill work capacity of less than seven METs at 85 percent of predicted age-adjusted maximum, and/or were rated as anxious or depressed by standardized psychological testing. The presence of any unstable cardio-vascular condition, or physical and psychological affilictions requiring treatment, were reasons for exclusion. After baseline testing, patients were randomly placed in one of three groups: exercise, group counseling, or

control. The exercise intervention consisted of three, 1-hour sessions per week for 12 weeks. Intensity was targeted at 85 percent of maximal heart rate achieved at baseline. Training was supervised by paramedical personnel with a cardiologist immediately available. Continuous electrocardiographic monitoring accompanied exercise. Patients of the group counseling set received 12 weekly sessions of 1-1 1/2 hours' duration led by a psychiatrist or social worker and a nurse clinician. Specific cardiac risk factors were discussed with emphasis on strategies for change. A pool of 999 referred patients was screened to find the 106 subjects ultimately selected for participation. Followup evaluations were conducted at 3 months, 6 months, and 1 year after entry into the program. There was one fatality from the control group during the study. Five subjects, three counseling and one each from the control and exercise group experienced a repeat infarction. CABG surgery was performed on four counseling and one control patient. No significant differences in the incidence of symptoms were reported among the three groups. Dropouts included five exercise patients and four from the counseling set. At 3 months, the exercise group demonstrated notably better work capacity than either control or counseling patients. After 12 months the three groups had achieved parity at the approximate level reached by the exercisers in 3 months. Counseling was found to reduce depression and enhance friendliness, independence, and sociability. The authors concluded that further research into the combined effects of an exercise plus psychosocial rehabilitation program was needed.

Roviaro and colleagues conducted a similar study in 1984 (67). Forty-eight male patients aged 69 years or younger who had an infarction or CABG surgery were included. All were at least 4 weeks past a cardiac event, clinically stable, and had no complicating medical or psychological

conditions. Stratification into an "acute" and "chronic" category was done based on an infarction or surgery less than 26 weeks before entry into the program (acute), and an interval that exceeded 26 weeks (chronic). There was a study group of 28 patients with 20 allocated as controls. Assignment was determined by distance from the hospital. Since the intervention occupied 3 days per week, patients who resided near the hospital received the scheduled exercise training while the controls received routine care. Cardiovascular function was measured at entry and repeated at 3 months. All other variables were evaluated 4 months later. The exercise regimen was based on peak heart rate achieved during an initial symptom-limited stress test. Supervision during the first 2 months of exercise was provided by paramedical therapists; during the third month patients monitored their own heart rates and activity. It was found that significant improvements in resting heart rate, treadmill time, and exercise blood pressure were exhibited by the study group compared with controls. When estimated, maximal oxygen consumption and double product values were derived from the exercise group data, Roviaro and others found significant improvement as well. Cholesterol levels did not vary between groups. Self-reported compliance with medical instructions over the final 4-month period of study was also significantly better among the group of rehabilitation patients. Their psychosocial measures of functioning showed improvement as did understanding of their disease. The authors concluded that the rehabilitation regimen resulted in a net benefit for the intervention group. Both chronic and acute patient subsets showed similar improvement.

May and Nagle investigated the effects of exercise and the progression of coronary heart disease on double product measurements over time (68). In an exercise physiology laboratory, 121 patients were stratified into three groups: an experimental group and two control groups. The experimental set

and one control set had baseline tests confirming myocardial infarction or severe myocardial ischemia. The remaining controls had tests that were within normal limits (their status with respect to coronary heart disease was not presented in detail). Ages ranged between 40 and 70 years. The experimental intervention consisted of supervised aerobic exercise of 10-12 months duration. Frequency and intensity were progressively scaled from 30 minutes daily up to 75 minutes twice weekly. A training heart rate was initially specified and maintained with progressively more intense exercise. At the completion of 1-year's training the experimental group showed a significant improvement in double product compared with the two control groups. The difference between control groups was not significant.

Ribeiro and others compared the effect of an exercise program with the combined effect of an exercise and dietary modification program in patients with coronary heart disease (69). Seventy-two patients with documented ischemic signs or symptoms were enrolled. All patients were given an initial evaluation that included symptom-limited bicycle ergometry. An average of 13 weeks of prescribed walking or bicycle exercise was performed by both study groups. Intensity was set at 80 percent of maximal heart rate for 30 minutes at least three times weekly. Exercise was observed by clinic staff once weekly to ensure that exertion was not excessive. In addition, the diet-exercise group were provided detailed instructions for a high-complex carbohydrate, low-lipid diet. Patients kept food diaries that were reviewed each week. Unfortunately, in the course of the study, patients were not randomly assigned to the two intervention groups. Both groups showed significant improvement in work capacity and a reduction in resting systolic blood pressure. Double product values did not change nor were they different between groups. Patients in the diet-exercise group experienced significantly

less angina on final stress testing than the exercise only group which led the authors to suggest that this was possibly due to the dietary intervention. Study results were not affected by beta-blocking drugs.

Hedback and others conducted a retrospective study of 297 patients 65 years and younger who were recovering from acute myocardial infarction (70). A nonselected intervention group of 143 consecutive cases who participated in a cardiac rehabilitation program 2 months after an acute event was compared with a similar group of reference patients that received conventional medical followup care. Rehabilitation of the study group began during acute hospitalization and involved early mobilization and educational activities. Baseline bicycle ergometry was performed 6 weeks after discharge. The rehabilitation patients then commenced a physicial training regimen that began with two weekly group sessions that merged into a home training program for the remainder of 1 year. Repeat exercise tests were performed at the 5-month and 12-month points after infarction. A 1-day dietary instruction course was included in this program. No initial significant differences in patient characteristics between subjects and controls were noted that might bias outcomes. Of the 143 patients in the intervention group, only 78 completed the exercise training program. Twenty were excluded at the outset because of severe cardiac or other medical complications. Thirty-nine declined to participate, and six dropped out, including three fatalities. Overall, there were nine deaths among the 143 patients selected to participate. At the completion of 1 year there was no difference between groups in total and cardiac mortality. The intervention group had significantly fewer nonfatal reinfarctions: 5.4 versus 16.2 percent. Total adverse cardiac events were also significantly lower in the exercise group: 13.3 versus 22.7 percent.

Smoking and hypertension declined in the intervention group as well. Patients who completed 12 months of physical training experienced a significant increase in work capacity when compared to their baseline performance.

As has been noted above, the World Health Organization (WHO) began a collaborative study of rehabilitation and secondary prevention after myocardial infarction in the 1970s (47). Twenty-four medical centers originally participated in this project. A randomized controlled protocol was developed with reinfarction and cardiovascular mortality as the end points. Lamm and others noted that the rehabilitation and control groups selected by the various centers were not completely compatible (71). Differences tended to favor the rehabilitation group. After 3 years of study only 17 of the 24 centers remained, representing 2,056 of 3,184 originally enrolled patients. The intensity of intervention also differed between centers (71). Results were inconclusive. Two centers showed a significant difference in mortality between groups, but in opposite directions. Overall, 11 centers had mortality that favored the rehabilitation groups, while 4 favored the controls. Nonfatal reinfarctions were less common among controls in nine centers while the rehabilitation groups had less in eight centers.

In 1985 Kallio and Cay reviewed the results of the WHO multicenter study (72). They concluded that end points other than death and reinfarction were not well defined and that there was a lack of adequate information on the care given to controls. Since they were drawn from academic centers, their "routine" care may have approximated that given to the intervention groups. Technical difficulties were also noted in decentralized project management and data collection. It was concluded that the study "failed to provide the answer to the question of whether or not comprehensive programmes, as practised in the participating centers, reduce long-term mortality and

reinfarction in patients who have had a myocardial infarction." Data related to quality of life was considered to lack validity. The work of researchers in the United States and Canada was also reviewed. A common problem of the National Exercise and Heart Disease Project and the Southern Ontario Multicenter Exercise-Heart Trial was identified (48,56). Both these studies had better than expected prognoses among their controls making statistical significance more difficult to attain. Selection criteria generally favoring the healthiest patients may be at fault in these and other studies.

The Lancet, in an editorial commentary concerning the WHO multicenter study, stated that "It would be more realistic to look upon rehabiltation programmes as a means of improving quality of life, particularly in the first year or two after an infarction" (73).

Considerable scientific attention has been attracted to the effects of exercise on myocardial function. Improvement in ventricular function, perfusion, and the stimulation of collateral coronary circulation to ischemic areas has been the focus of most studies (41,51-53).

Rerych and others studied the effect of a maximal exercise regimen in 18 healthy athletes (74). Radionuclide angiography was performed before and after 6 months of swimming training. It was found that cardiac output during maximal exercise increased, largely as a result of enhanced cardiac dilatation from rest to exercise and the ability to eject this increased end-diastolic volume at the same or a lower heart rate. Cardiac output at rest remained the same but heart rate had decreased after training. It was concluded that intensive training can increase the capacity of the normal heart to function effectively at rest and during periods of maximal output.

Hung and coworkers evaluated changes in myocardial perfusion and left ventricular function in clinically uncomplicated postinfarction patients after

exercise training (75). Fifty-three consecutive male patients under 70 years of age were randomized to a training or control group. Symptom-limited treadmill testing with thallium perfusion and radionuclide ventriculography was performed at 3, 11, and 26 weeks after acute infarction. The 23 patients trained at home on stationary bicycles to 85 percent of age-predicted heart rate. Heart rate and transtelephonic electrocardiographic monitors were supplied to these patients. Exercise cardiograms were transmitted twice weekly. No complications of exercise training were encountered. It was found that significantly higher bicycle work capacity was attained by the intervention group, however it was attributed to an increase in peak exercise heart rate. No differential improvement in myocardial perfusion or left ventricular function was detected in the study group. A degree of improved perfusion occurred spontaneously in both control and exercise patients between the 3rd and 26th weeks after infarction.

Although exercise has been used extensively in the rehabilitation of patients with coronary heart disease, Ehsani and coworkers have argued that the levels of exertion commonly employed may lack sufficient intensity to alter ventricular performance (16,28,76,79). A series of studies was performed to measure the effects of prolonged intense endurance exercise training on myocardial function. Their patients were generally selected for the purpose of testing this hypothesis rather than as subjects in a conventional cardiac rehabilitation program. For this reason, the ability to successfully complete at least 1 year of intensive endurance exercise was a significant criterion for participation. Patients were under 65 years of age and had various forms of documented coronary artery disease. Exercise testing was performed initially and at the termination of the training program in accord with a protocol that involved both treadmill testing and bicycle

ergometry with direct measurement of oxygen consumption. Ehsani has noted that the most objective indication that maximal oxygen uptake capacity has been reached during exercise is the attainment of an oxygen uptake plateau despite an increase in work rate (16). The authors observed that increased total coronary blood flow and the development of coronary collaterals have not been demonstrated in humans as a result of high-intensity exercise training. However, their work has demonstrated improvement of myocardial functioning in several groups of patients after prolonged training at an intense level of exercise. Ten such patients were able to achieve a 22 percent increase in the double product value at which S-T depression occurred during exercise (76). Ehsani and colleagues contended that lesser levels of exercise training had previously been unable to vary the relationship between the magnitude of S-T depression at a given value of double product. Thus, the maintenance of a stable level of S-T depression at maximal exercise, with an increased double product, was taken to suggest an increased index of myocardial oxygen consumption resulting from training. The program of prescribed exercise included walking, jogging, or bicycle ergometry. Intensity was progressively increased to 1 hour daily, 5 days per week reaching up to 90 percent of maximal oxygen consumption for 2-5 minutes each session. Left ventricular performance and diminished electrocardiographic criteria of ischemia are beneficial effects that Ehsani attributed to intensive prolonged endurance training (16,28,77,79). Medical supervision of this high-intensity training was considered mandatory; however, monitoring arrangements were not specified (16). Patients who could not tolerate the prescribed exercise regimen for any reason were withdrawn from the various trials. Control groups were not employed in study design. Corollary findings of these studies involved the effects of exercise on plasma catecholamines and lipids (80,81). Ehsani and

others suggested that norepinephrine concentrations, at a given exercise level, tended to be lower after physical training and might provide a protective effect against exercise-induced arrhythmia in some patients (80). In the presence of a progressively higher intensive training program, the maximum attainable level of plasma norepinephrine may exceed pretraining levels. Heath and others also found that endurance exercise tended to reduce plasma cholesterol, low-density lipoprotein-C, and triglyceride concentrations, while high-density lipoprotein-C levels increased (81).

In a companion study, Hagberg and others compared the hemodynamic responses of young and older endurance athletes with those of healthy, older sedentary subjects (82). He found evidence to suggest that older athletes do not experience a decline in ventricular stroke volume with age; a tendency that normally occurs with aging in sedentary individuals. A lower maximal heart rate was also found among the older athletes which matched the responses of younger athletes. Peripheral vascular resistance was noted to be 15-20 percent higher among older athletes when compared with the younger group, but was consistently lower among all athletes than the sedentary subjects.

In 1985, Williams and associates reported on a study that compared the results of exercise training among cardiac patients who were stratified by age (83). Enrolled in the training program were 361 men who had experienced a coronary event within 6 weeks prior to the study: 166 after infarction and 195 after CABG surgery. Patients with complications or unstable disease were excluded. Seventy-six of the 361 participants were over age 65 (range, 65-85 years). Of this number, 41 had infarctions and 35 were post-CABG. Symptom-limited treadmill testing was performed before and after an exercise training program that lasted for 12 weeks. Three, 40-minute exercise sessions were given each week with continuous single-lead electrocardiographic monitoring.

Prescribed intensity was between 70 and 85 percent of the maximal heart rate attained during the initial exercise test. Attendance was 90 percent among the elderly group with no adverse events reported during testing or training. This group showed a significant decrease in body weight and body fat composition after the exercise program. Work capacity measured in METs increased from 5.3-8.1 while heart rate at rest with maximal exercise decreased significantly as did the average submaximal double product. Although the absolute work capacity of the over 65 group was significantly lower than that reached by the younger groups, the magnitude of favorable change was equivalent. Patients receiving beta-blocking drugs also responded proportionately when compared with those not taking such medications. It was concluded that elderly male cardiac patients benefit from early exercise rehabilitation "through enhanced functional capacity and improved psychological responses to exertion." No additional risk due to greater age was found.

There have been a number of studies to investigate the value of cardiac rehabilitation services for patients who have undergone CABG surgery. In 1981, Weiner and others examined the duration of functional benefit from CABG by means of serial exercise testing that began before surgery and extended for up to 4 years thereafter (84). Among 111 patients with presurgical angina, he found increased double product and functional capacity as well as decreased electrocardiographic indication of ischmia at 6-18 months after surgery. In a smaller group of 20 patients followed for 37-48 months, the initial improvement in exercise test performance was found to persist, but the frequency of positive tests increased. Thus, improvement was measurable for up to 4 years with declining benefits in some patients over time.

Similar results were reported by the Coronary Artery Surgery Study (CASS) (85). A group of 780 patients with more than 70 percent stenosis of one or more operable coronary vessels was randomly assigned to surgical or medical therapy. Systematic followup was accomplished for a mean of 5.5 years. Treadmill exercise testing was performed initially and at 6, 18, and 60 months after entry. The study showed that CABG surgery "improves the quality of life as manifested by relief of chest pain, improvement in both subjective and objective measurements of functional status, and a diminished requirement for drug therapy." Recognized cardiac risk factors remained unchanged, and no significant effect on employment or recreational status was noted. If days of hospitalization for the CABG surgery are excluded, the frequency of hospital admissions between groups was comparable. Survival was equally good among surgical and medical groups. Confirmation of functional improvement in the surgical patients was based on longer treadmill work times with less angina and less S-T depression.

Oldridge and others studied the effects of aortocoronary bypass surgery supplemented with 32 months of prescribed physical conditioning (86). Twenty-one men with coronary heart disease, age 36-63 years, were given symptom-limited treadmill tests prior to revascularization and at 16 weeks postoperatively. Exertional angina was alleviated in 20 patients. Postsurgical functional capacity and double product were also significantly better. At the 16-week point, six patients who resided near the hospital were enrolled in an ongoing, regular, supervised physical training program. At the end of the training period, they were compared with six of the original patients who had not undergone any regular form of physical training. Prescribed training consisted of three weekly sessions of 1 hour each based on achieving a heart rate of 65-75 percent of tested functional capacity. It was

found that the six subjects who participated in physical conditioning had an improvement in treadmill functional capacity of 28 percent as contrasted to an improvement of 3 percent in the six controls. A corresponding improvement in double product was also seen in the intervention group. The level of physical fitness attained in the conditioned patients was considered to be comparable with that of healthy males of similar age in the general population.

Waites and colleagues performed a retrospective study of two groups of 11 post-CABG surgery patients to assess the effects of an exercise rehabilitation program (87). The exercise intervention group was participating in a three-times-weekly, 1 hour per session program with a coronary risk factor educational component. These patients were at least 9 months postsurgery and had attended for over 6 months. Exercises were individually prescribed and medically supervised. Intensity was not specified. The 11 patients in the control group had dropped out of outpatient rehabilitation training after CABG surgery. Participants in the exercise program were found to have greater functional capacity and submaximal oxygen consumption than controls. They were more likely to be working fulltime, have fewer rehospitalizations, and less likely to smoke. The potential bias of selection factors associated with adherence to the structured program was acknowledged.

The effects of exercise-based rehabilitation after surgery for myocardial revascularization was the subject of a randomized prospective trial conducted by Foster and others (88). Of 28 patients undergoing surgery, 19 were assigned to a high-level aerobic exercise group and 9 were controls who were given muscle relaxation training and low-level exercise. Exercise testing with radionuclide angiography was performed prior to surgery, and postoperatively at 2, 8, and 24 weeks. Both groups were given a three-times-weekly program, which was designed to improve work capacity among the

intervention set, but not among the control patients. It was found that even when exercise is limited to relatively low levels, as was the case in the control group, work capacity still improves significantly after revascularization surgery, although the exercise intervention group manifested greater benefits at 24 weeks compared with the controls. An absolute need for control populations in studies of this nature was emphasized. No significant effect on left ventricular ejection fraction was seen in the exercise group. Increased work capacity of "considerable magnitude" was considered a normal corollary of the healing process that was beneficially modified by the formal rehabilitation program. A smaller number of rehabilitation patients who were reexamined 1 year after surgery and 6 months after finishing formal rehabilitation showed a decline in work capacity, possibly attributable to withdrawal of social support provided by the program. Foster concluded that the mechanism of enhanced work capacity stemming from rehabilitation remained unclear.

Froelicher and associates also studied the effects of exercise therapy after CABG surgery (89). Fifty-three male volunteers between 35 and 65 years were randomly assigned to an exercise intervention group or a control group at least 4 months after CABG surgery (range: 6 months-9 years). They were exercise tested with thallium scintigraphy, electrocardiography, and oxygen uptake at the beginning of the investigation and after 1 year. About one-third of the cases had signs or symptoms of ischemia indicating surgically unresolved problems. The intervention group trained at 80-85 percent of maximal heart rate three times each week. No cardiac complications of exercise were encountered. There were two medical dropouts in each group. A member of the exercise group also dropped out for social reasons. It was found that the exercisers had significant increases in oxygen uptake and

declines in both submaximal and resting heart rate. These benefits were seen in patients with and without angina. Observed changes in thallium perfusion studies were not statistically significant.

In a review of cardiac rehabilitation following CABG surgery, Murray and Beller commented on the need for an exercise conditioning program (90). They noted that the results of surgery may be limited to symptomatic benefit and that progressive symptomatic deterioration tends to occur in the presence of unmodified cardiac risk factors. On the other hand, exercise conditioning may serve to maintain or increase functional capacity without causing angina or other symptoms.

Compliance with prescribed exercise regimens and its effect on both cardiac status and psychosocial outcomes has been of interest to a number of researchers. Bruce and associates retrospectively analyzed their experience with 603 enrollees of the Cardiopulmonary Research Institute (CAPRI) community programs for rehabilitation (91). The patients performed 30-60 minutes of medically supervised exercise 3 days each week. It was found that 58.4 percent had dropped out after an average of 8.6 months for men and 5.7 months for women. There were significant differences that might have aided in distinguishing potential dropouts from continuing participants. Among the active enrollees, attendance at scheduled sessions was about 70 percent. However, virtually all participants completed the initial 3 months of basic training. This was considered sufficient to achieve some functional benefit. A confounding element in cardiac rehabilitation research involves the evaluation of dropouts. The possibility that patients with progressive disease leading to diminished performance might be most likely to abandon the program was noted. About 40 percent of the dropouts continued some form of

physical activity on their own initiative, but the significance of this data in relation to the functional status of the nonexercising dropouts is not clear.

Carmody and others acknowledged that long-term maintenance of exercise regimens was problematic, commenting that dropout rates varied among cardiac rehabilitation programs (92). They followed 203 patients in a supervised community program for 40 months. The subjects were to attend three, 1-hour sessions per week. Prescribed exercises targeted the attainment of 85 percent of maximum heart rate except where contravened by symptoms. It was found that the dropout rate was greatest during the early months of the program and declined with time. Twenty-three percent of the had dropped out during the first 3-month period, 30 percent had left at 4 months, 52 percent by 1 year, and 81 percent had defected at the end of 40 months. Parallels between the rates of dropouts and the "group relapse curve" employed in social science research were recognized. Reinforcement and associative learning techniques were deemed productive areas for future cardiac rehabilitation research.

Shephard and associates followed a group of 610 men in their fourth and fifth decade through 3 years of an exercise-centered cardiac rehabilitation program (93). Exercise was monitored periodically and consisted of a daily distance to be covered in a specified time. Subjects experienced an infarction anywhere from 2-109 months previously. During the period of observation there were 21 nonfatal reinfarctions, 23 fatal recurrences, and 12 "unrelated" fatalities. For purposes of analysis, these 12 unrelated deaths were removed from the study sample leaving 598 subjects of whom 100 failed to "comply fully" with the exercise regimen. An association was found between poor compliance with exercise and an adverse prognosis following infarction. A fivefold improvement in the odds ratio for both fatal and nonfatal

recurrences was noted among active exercisers which persisted when the patients were stratified by most categories of cardiac risk factors. Compliance was adversely affected by angina on either initial or final testing. ST-segment depression during exercise testing had no effect on compliance, but was found to be a significant predictor of both fatal and nonfatal reinfarction. A direct cardiac benefit from exercise compliance could not be causally established since the association was recognized to be susceptible to indirect influences not controlled in the research design that was employed.

In 1984 Oldridge reviewed the reported experience with compliance and dropout in cardiac rehabilitation programs (22). He found that a majority of studies showed a 30-50 percent dropout within 12 months and 45-80 percent at 48 months. Some patients were excluded from rehabilitation on various medical and nonmedical grounds that may differ among programs. The candidates who ultimately began exercise regimens tended to go through a process of self-selection that Oldridge considered to be influenced by content, environment, and supervision, among other variables. He noted that although single factors were not clearly associated with compliance or dropout, smoking and blue collar status were likely predictors of dropping out. Conversely, nonsmoking and white collar occupation correlated with compliance. The presence of overweight and inactive leisure habits were also associated with dropout. The goals of cardiac rehabilitation services encompass adoption of positive lifestyle changes including a sustained level of appro- priate exercise. Oldridge concludes that prediction of compliers and dropouts as well as design and testing of interventions that reliably influence patient behavior are of compelling significance.

Haynes also examined compliance problems in cardiac rehabilitation (20). He emphasized the need for the informed participation of willing patients with specifically determined diagnoses in programs of scientifically established efficacy. Behavior modification strategies were advised in preference to informational approaches to compliance. The tendency of some researchers to use attendance at exercise sessions as a measure of compliance was considered invalid as are fitness outcomes when measuring adherence to regimens. Haynes commented that such outcomes are frequently determined by factors outside of the program. He concluded that "noncompliance is one of the most important reasons for lack of definitive evidence concerning the efficacy and effectiveness of exercise and is a problem that must be confronted." Additional methodologically sound studies were considered necessary.

Safety

Concern over the safety of cardiac rehabilitation services has centered on the exercise therapy component. The three areas of principal interest have been exclusionary criteria for patient selection, the nature of professional supervision, and the need for electrocardiographic monitoring during exercise sessions.

Siscovick and others have estimated the rate of primary cardiac arrest during vigorous exercise in a healthy population of exercisers to be 0.55 per 10,000 men annually (94). They studied 133 men between 25 and 75 years without known heart disease who experienced sudden cardiac death while exercising. When these cases were matched with a comparable group randomly selected from the general population he found a significant indirect

relationship between intensity of habitual activity and risk of cardiac arrest. A sedentary lifestyle was associated with 56 times more risk of death during intense exercise. The risk of cardiac arrest among habitual exercisers was five times greater during intense activity, but their overall risk of sudden cardiac death was 40 percent less than that of sedentary men. Paffenbarger and associates has also found a lower risk of death among habitual exercisers when compared to a sedentary cohort (23,95).

In 1984, Haskell reviewed the published experience with exercise as an element of cardiac rehabilitation (36). He found that most program guidelines recommended large muscle dynamic exercise for 30-60 minutes per session at least three times per week. An intensity of 60-75 percent of measured functional capacity in METs or 70-85 percent of peak heart rate on a symptom-limited exercise test has commonly been specified. Although many programs have emphasized full-time medical supervision to ensure safety, Haskell noted that it may not be necessary for low-risk patients. Medical supervision is also a major contributor to program costs and may be a factor in accessibility where physicians are not locally available. Two technical safeguards against cardiac complications are an appropriately calibrated exercise prescription, and electronic monitoring of heart rate or electrocardiogram. Both medical and nonmedical supervision have also been used to assure patient compliance with exercise limits and avoid complications due to excessive exercise intensity. Sudden ventricular fibrillation, cardiac arrest, and infarction are the principal cardiac events precipitated by an increase in myocardial workload. Haskell also explained that with increasing heart rate, diastolic filling time decreases, thus reducing coronary artery circulation and increasing the risk of ischemic damage. The increases in circulating catecholamines, sodium-potassium imbalance, and circulating free fatty acids

seen with intensive exercise are also cited by Haskell as conducive to arrhythmia. It was suggested that an exercise plan be developed for each patient that "will result in a myocardial workload that is below the level at which medical contraindications to unmonitored exercise occurred during a symptom-limited exercise test." Exercise therapy was considered unsuitable for patients of unstable clinical status. Haskell had remarked in an earlier publication that patients with a low physical work capacity who could not increase their capacity after 6 months of reliable participation in a physical conditioning program should be reevaluated and considered for alternative therapy (96). However the probability that a specific patient may develop a new adverse cardiac event cannot be calculated in terms of prescribed exercise intensity so that trade-offs might be arranged. The ability to accomplish a symptom-free workload of 7-8 METs during an exercise test was considered generally predictive of the ability to perform sustained isometric work "without any indications of myocardial dysfunction."

The most frequent medical complication of exercise therapy requiring emergency intervention was found to be ventricular fibrillation (36). Successful resuscitation was said to be possible in about 90 percent of cases when personnel skilled in defibrillation were present.

In 1978 Haskell surveyed the occurrence of cardiovascular complications among patients enrolled in 30 cardiac rehabilitation programs in the United States and Canada (97). Exercise classes were conducted at 103 sites for 13,570 participants who received 1,629,634 patient hours of medically supervised cardiac exercise. All locations had the capability to provide cardiopulmonary resuscitation including emergency medications and electrical defibrillation. Data were collected from the 30 centers by mail questionnaire with a response rate of 100 percent. The mean time after an infarction or

CABG surgery before a patient began an exercise program was 9 weeks (range, 2-12 weeks). A mean of three sessions per week was recommended. Two of the programs, accounting for 352,000 patient hours of exercise, employed continuous electrocardiographic monitoring every session. On the average, each patient attended 111 sessions, or three times per week for 37 weeks. A total of 61 major cardiovascular complications occurred. They were classified as "cardiac arrest, myocardial infarction, or other, and as fatal or nonfatal." Fourteen fatalities and 47 nonfatal arrests or infarctions were reported. Of 50 cardiac arrests, 42 (84%) were resuscitated, and 5 (71%) of 7 patients with infarctions recovered. The remaining four fatalities involved two cases of pulmonary embolism, one case of pulmonary edema, and one case of cardiogenic shock. Overall, cardiac arrest was the most common complication, with a frequency of one event per 32,593 patient hours. Infarction occurred once every 232,809 patient hours. A fatality was reported for every 116,402 hours of exercise. If all complications, both fatal and nonfatal, are aggregated, the incidence was one event for each 26,715 hours. The two programs with continuous electrocardiographic monitoring representing 3,940 patients at 70 class sites experienced only three cardiac arrests all of which were nonfatal. Overall, programs with continuous monitoring reported one event every 22,028 hours of patient participation while the programs with medical supervision, but without continuous monitoring, had one complication per 117,333 hours. The difference between these rates is statistically significant. There was sufficient diversity of other program characteristics to prompt caution on the part of the author in attributing the reduction of complications solely to cardiographic monitoring (36,97). He commented on the need for systematic study of this issue.

Patient selection criteria that include the triage of cases into risk categories for prescribing of exercise and determining the required level of supervision were also discussed by Haskell (36). His work with DeBusk on stratification of risk and in-home cardiac rehabilitation with periodic transtelephonic monitoring has already been noted (13,32). On the other hand, Simoons and others, in a study of 40 patients with coronary heart disease, found that selection of patients with high risk for arrhythmia for an exercise rehabilitation program based on exercise testing or ambulatory electrocardiographic monitoring was not feasible (98). Neither the exercise stress test nor ambulatory monitoring were accurately predictive of the type of arrhythmias seen during the rehabilitation program. Haskell has argued that since the type of arrhythmia seen during exercise therapy rarely leads to ventricular fibrillation or cardiac arrest, such activity is safe in otherwise low-risk patients (36).

Fagan and others reported on a 5-year experience with ventricular arrhythmias among 2,267 attendees of an Australian cardiac rehabilitation program (99). All had begun training between 3-6 weeks after an infarct or CABG surgery. A total of 62,733 patient hours of medically supervised exercise was involved, with each patient having attended an average of 18.5 sessions of 1.5 hours apiece. Fourteen patients developed serious ventricular, arrhythmias among which was one fatality. The complication rate for cardiac arrest was one event per 20,911 patient hours. In concordance with Haskell, it was found that complications during exercise were unrelated to the time elapsed since the original cardiac event preceding entry into rehabilitation. Because of this unpredictability, Fagan advised close supervision, the ready availability of resuscitation equipment, and electrocardiographic monitoring during "all phases of exercise." The overall

rate of ventricular fibrillation and tachycardia for the 5-year period of study was 0.62 percent. Selection criteria for these patients were not specified.

DeBusk and associates compared at-home rehabilitation with group rehabilitation in 127 men with clizically uncomplicated acute myocardial infarction (32). They found that compliance, benefits, and dropout rates were quite similar. The patients were selected on the basis of a stepped process of clinical evaluation that included exercise testing 3 weeks after the acute event and telephone surveillance of exercisers. No training-related complications befell either home or group subsets. Cardiac exclusions from participation were unstable angina pectoris, valvular heart disease, atrial fibrillation, bundle branch block, and a history of CABG surgery. Of 66 patients engaged in home training, 20 manifested ventricular arrhythmias during telephonic monitoring, but none were required to withdraw from the rehabilitation program. Since other authors have related exercise-induced cardiac arrest to the intensity of training, DeBusk provided his patients with portable heart rate monitors to assist them in maintaining their pulse within prescribed limits.

Erb and associates recommended that individuals with documented myocardial infarction, stable angina pectoris, cardiovascular surgery, or who are vulnerable to premature coronary heart disease due to significant risk factors, are appropriate candidates for cardiac rehabilitation services (31). Absolute contraindications to participation were not given; however, an extensive list of complications was presented with the suggestion that patients with such complications require "special precautions before engaging in exercise treatment programs." Physician supervision and an exercise prescription based on "the exercise test, the patient's medical state,

coronary risk profile, attitude toward exercise, motivation and musculoskeletal stability" was recommended. Review of the exercise prescription at least every two weeks was considered desirable. The presence of a physician during exercise sessions was endorsed, and periodic electrocardiographic monitoring of one in three sessions (decreasing with time) was also suggested.

In designing the National Heart Disease and Exercise Project, Stern and associates also developed exclusion criteria for patients (66, 100). They included:

1. Significant coexisting cardiovascular disease
2. Complete atrioventricular block with or without ventricular pacemaker
3. Diastolic BP measured in excess of 100 mm Hg when at rest in a supine position on three consecutive visits
4. Coexisting disease that made long-term survival unlikely
5. Uncontrolled diabetes mellitus
6. Participation in another formal exercise program
7. Physical and/or emotional impairments judged to preclude the patient's participation and adherence to a physical activity program
8. Failure to sign informal consent.

In 1986 a large group of investigators published a scheme for identification and treatment of low-risk patients after acute myocardial infarction and CABG surgery (101). They concluded that by 3 weeks after hospitalization it was possible to recognize the 50 percent of patients who will have less than 2 percent annual mortality. This was accomplished by means of clinical observation, exercise testing, and other noninvasive tests. The patients in this category were considered a low-risk group and

therefore amenable to more aggressive cardiac rehabilitation measures including progression to home exercise. At least 300,000 Americans who annually survive an infarction were stated to be at "low risk of reinfarction or death and have no limiting medical or musculoskeletal conditions." They estimated that "home training is possible for the 255,000 low-risk patients who do not participate in group training programs." Similar guidelines for assessing prognosis in CABG patients were also proposed with the caveat that the prognostic value of exercise testing was not well established. Preoperative and postoperative exercise tests were, however, viewed as valuable in measuring functional capacity.

Fardy and others reported on their experience with continuous electrocardiographic monitoring of exercise therapy in 100 outpatients participating a 12-week cardiac rehabilitation program (35). They found that 16 percent of patients had "serious" cardiac events during the initial 7 weeks of exercise sessions while the rate dropped to 13 percent in weeks 8-12. It was concluded that the risk of serious arrhythmias and ischemic sequelae was sufficiently high to warrant full-time monitoring during prescribed exercise.

In 1983 Franklin reviewed the published data on continuous monitoring in cardiac exercise programs (102). He estimated the costs of continuous monitoring to be $15-60 per session and noted that they compared favorably with the alternative of repeated exercise stress tests to follow patient progress and detect adverse prognoses. It was concluded that further research on monitoring was needed. As a result, Mitchell and associates studied the value of continuous monitoring in 177 participants in a 4-week cardiac exercise program 3 days per week (103). The patients ranged in age from 25-75 years and were selected after screening to exclude individuals with medical

complications or the inability to perform workloads greater than 3 METs. A majority of the group were post-CABG surgery (52%) and 72 percent of patients were within 4 months of a coronary event. There were 2,248 patient sessions (1,686 exercise hours) involved. Twelve patients demonstrated "new or significant ECG or blood pressure abnormalities" that were not evident on initial exercise testing. Eleven of these abnormalities (92%) occurred in the first 3 weeks of the program. A 7 percent independent diagnostic yield was credited to the monitoring of exercise therapy. The investigators concluded that a 4-week program of continuous electrocardiographic exercise monitoring is probably adequate for patients "who undergo careful preliminary screening."

A further elaboration on continuous electrocardiographic monitoring during exercise training was reported by Baird in 1985 (104). One hundred fifty patients with coronary heart disease were evaluated with symptom-limited "provocative" exercise in a 6-week rehabilitation program comprised of three sessions each week. Patients with intractable arrhythmias, unstable angina, congestive heart failure, or left main coronary artery disease were excluded. The initial training sessions were used to establish a baseline prior to beginning drug interventions. In effect, the continuously monitored exercise sessions that followed were employed to titrate dosages for optimal alleviation of signs and symptoms disclosed by the initial provocative exercise test. Of 121 patients with ischemic heart disease, medical management was considered successful in 103 (86%). A control group was not used.

The available information on the efficacy and safety of cardiac rehabilitation services has been reviewed in print by a large number of commentators in recent years. In 1971, Fox and associates stated that

participation in a structured exercise program three times per week could increase the physical work capacity and sense of well-being of sedentary individuals (105). An intensity of 70 percent of age-adjusted, predicted maximum heart rate was considered appropriate to achieve these gains. They favored activities that augmented endurance capacity rather than strengthbuilding exercise. A series of hypotheses was advanced whereby the severity of coronary heart disease might be reduced by an increase in habitual physical activity.

Greenberg and others found the evidence on the effect of sustained exercise on longevity and reinfarction to be equivocal in 1979 (106). They concluded that the increase in physical work capacity seen after training is predominantly as a result of increased oxygen extraction by peripheral muscles. Thus, some patients perform the same amount of submaximal work after training at a lower heart rate, and lower double product, with a resultant decrease in myocardial oxygen demand. In the opinion of the authors, the relative bradycardia induced by exercise prolongs diastole and allows for increased coronary artery filling. However, they noted that the question of home versus supervised exercise clinics was unresolved. The physiologic principles underlying cardiac exercise training programs were considered sound.

Amsterdam and colleagues proposed that aerobic (endurance) exercise training can lead to increased functional capacity in cardiac patients with and without angina and metabolic changes that reduce atherogenic-thrombogenic potential (107). These beneficial changes were ascribed to peripheral physiologic adaptations. They concluded that "utilizing established methods of evaluation, investigators have demonstrated no evidence of augmented

ventricular function, regression of coronary obstructive disease, increased development of coronary collateral vessels, rise in coronary blood flow, or improved myocardial oxygenation."

May and associates reviewed the efficacy of various long-term interventions designed for secondary prevention after myocardial infarction (24). Six studies of physical exercise were included in this report. Although none of the exercise trials had shown a statistically significant reduction in mortality, it was found that most had a positive trend favoring the physical training group that varied from 21-32 percent. The results of the six studies were pooled, and a statistically significant (19 percent) reduction of mortality among the exercise intervention groups. However, such aggregation of data was conceded to be problematic. Overall, the six trials were too small to reveal independently reliable results.

Shephard pooled the data from three controlled trials of exercise in ischemic heart disease that involved 1,318 patients (108). He concluded that over a 4-year period the subjects who exercised had a significant 25-35 percent reduction in mortality when compared with controls. They had fewer reinfarctions and fewer fatal reinfarctions. It was noted that the effects of physical training were greatest in the first 2 years of rehabilitation with a decline in compliance thereafter. The limitations of data-pooling were discussed. In a later commentary, Shephard attributed the benefits of cardiac rehabilitation to: reduced myocardial irritability, secondary to decreased release of catecholamines; reduced cardiac work rate, which is a result of training bradycardia and a smaller rise in blood pressure; and improved coronary perfusion secondary to training bradycardia (109).

Rigotti and associates reviewed the epidemiologic evidence on physical activity and the development of coronary heart disease (110). They concluded that available data do not yet support an assertion that exercise training favorably impacts survival after an infarction. A positive trend was discerned, but evidence was acknowledged to be inconclusive. On the other hand, persuasive evidence was found that exercise training can enhance the ability of patients to tolerate increased levels of physical activity. This increase in functional capacity was attributed to beneficial peripheral changes, not myocardial adaptation. Rigotti and associates stated that these exercise-induced peripheral effects allow the heart to do less work at any given workload. The double product was seen as the best measure of myocardial oxygen consumption for determining cardiac workload. Psychological benefit from regular exercise in cardiac patients was also identified. Evidence supporting an exercise-effect on myocardial perfusion was termed "sketchy." The total effect of exercise training on cardiac risk factors among those who already have coronary heart disease was noted to be inconclusive, but an increase in HDL-cholesterol was considered to have been reliably demonstrated. In summary, Rigotti's group found that conclusive proof of the preventive role of exercise in coronary heart disease was not available. However, they found that "the evidence is sufficiently strong to support the recommendation of exercise as part of a program to decrease the risk of coronary heart disease and as part of therapy for patients with coronary artery disease."

Franklin and associates also agreed that regular endurance exercise training can augment physical work capacity and mitigate angina pectoris in many patients with coronary heart disease (30). They commented that peripheral adaptations appear largely responsible for the improvement in

functional capacity that is seen during the early months of cardiac exercise training, but cite the work of Ehsani and others as evidence of later myocardial adaptations (28). Nevertheless, the effects of physical training on myocardial perfusion and development of coronary collateral circulation were seen as unproven in humans. The controversial nature of exercise trainability in patients using beta-blocking medication was also mentioned. Franklin and associates presented a very comprehensive review of the physiology of physical conditioning. They concluded that cardiac risk factor reduction, enhanced physiologic status, and improved quality of life "appear to be sufficient end points to justify the recommendation for physical conditioning in patients with coronary heart disease."

In 1984, Staniloff reviewed the literature of cardiac rehabilitation (38). He found a shift in emphasis that favored an improvement in quality of life over claims of decreased mortality due to rehabilitation programs. By pooling of data from six studies, Staniloff concluded that convincing evidence of a life-prolonging effect indeed existed. A decrease in risk of future cardiac events was also noted to be calculable. With respect to the need for continuous monitoring, a trend toward inclusion of sicker patients in structured and monitored rehabilitation settings was discerned while healthier patients appeared to be exercising without monitoring. Equal accentuation of exercise, diet, and psychological aspects of patient recovery was noted.

Naughton reviewed clinical trials in which physical activity was the major therapeutic intervention (111). He found that the total number of patients with myocardial infarction who have been studied was small and that "selection has favored the low-risk cardiac patient." In the absence of patients representing a wide range of severity, questions related to detrimental cardiovascular effects of exercise remained unresolved in the

author's opinion. He stated that significant physiologic changes had been induced in patients provided cardiac rehabilitation services with a trend toward reduced mortality. Their effect on morbidity, specifically reinfarction, was considered to remain undetermined. Compliance with exercise regimens on a long-term basis was noted to be problematic and required special efforts to educate supervisory staff to enhance participation. In conclusion, Naughton felt that sufficient reasons exist to recommend therapeutic physical activity to selected, highly motivated patients with coronary heart disesase; however, further scientific studies were said to be needed regarding the appropriate application of these techniques.

Roman concurred with other commentators in 1985 when he decided that the available, well-randomized and controlled clinical trials had not demonstrated a significant reduction in mortality and morbidity due to cardiac rehabilitation although a favorable trend might exist (112). He suggested additional attention to issues such as improvements in the quality of life.

Hammond discussed the evidence and rationale underlying the role of exercise in the management of coronary disease (113). He found improved physical work capacity and maximal oxygen uptake to be predictable benefits. It was suggested that activity levels previously associated with angina in stable patients could be reached without symptoms after exercise training. A small subset of patients were considered to develop primary beneficial myocardial changes, but the mechanisms involved were said to remain unverified. Exercise was recommended as a primary modality in the care of cardiac patients.

DeBusk and associates reviewed data from a number of medical centers on the identification and treatment of low-risk patients after infarction or CABG surgery (101). They noted that the natural process of recovery generally

involves a substantial increase in functional work capacity during the 6 months following an acute infarction. Individually prescribed progressive exercise training, beginning 3 weeks after an event, was acknowledged to augment the spontaneous improvement in functional capacity that typically occurs. They endorsed home-exercise for low-risk patients following a few weeks or months of group participation. Symptom-limited maximal exercise testing was suggested as an aid in identifying low-risk patients. Because of the small enrollment of most reported studies, the intrinsic low risk of enrollees, poor compliance, and other confounding factors, the independent benefits of exercise therapy were found to be unclear. In patients recovering from CABG surgery, an appreciable increase in functional capacity can be expected on treadmill testing 4-6 weeks postoperatively. Aside from a caveat regarding physical disruption of the incision, the authors considered physical activity after CABG surgery to be governed by the same principles as those for acute infarction.

In 1986 Bairey examined the relationship of exercise and coronary artery disease (114) in light of the American College of Sports Medicine's (115) recommendation that people should exercise at least 30 minutes per day three times each week to 70 percent of maximal predicted heart rate in order to achieve cardiovascular health. Documentation of the safety of supervised exercise with coronary heart disease was recognized. Conclusive evidence that exercise alters the progression of atherosclerotic lesions or has an impact on morbidity and mortality was not found. In addition, although exercise may be beneficial in reducing many cardiac risk factors, Bairey found little evidence of an independent association between a specific risk factor and exercise. However, she concluded that overall, the weight of evidence indicates that

exercise improves the cardiovascular risk profile. Pre-exercise treadmill testing was proposed for patients with known coronary artery disease or having symptoms suggesting cardiac disease.

O'Connor and others reviewed 27 published reports of randomized clinical trials of exercise after myocardial infarction (116). Only one achieved statistically significant results. The results were aggregated to compose a sample of 3,861 patients with an average of 3 years of followup. Analysis was based on a weighted average of relative risk for each study using total mortality, cardiovascular mortality, sudden death, and both fatal and nonfatal reinfarction as end points. A significant reduction in total and cardiovascular mortality of 20-25 percent was attributed to the influence of exercise programs following myocardial infarction.

Published guidelines for the establishment and conduct of therapeutic exercise programs intended for individuals with and without coronary heart disease have been available for a number of years (31,37, 117-119). The State of North Carolina now requires that cardiac rehabilitation programs be inspected and certified. A set of rules governing certification for licensure and compliance has been issued (120). There is general agreement that enrolled patients shall be under medical supervision with a staff on hand that is skilled in resuscitative techniques. Exercise testing is usually mentioned as an important element in the development of an exercise prescription and as an indicator of progress. To date, there is a paucity of integrated research concerning the efficacy of such guidelines as determinants of health status outcomes.

DISCUSSION

Structured cardiac rehabilitation services represent an organized multidisciplinary effort to address the complex medical and psychosocial needs of individuals with a chronic impairment: coronary heart disease.

With convalescence from an acute coronary event such as myocardial infarction, CABG surgery, or, perhaps, newly diagnosed coronary heart disease, Wenger has discerned a "need to assess the role, safety, and effectiveness of unsupervised exercise" (1). Patients have an acknowledged role in the management of their disease based on education and an accurate assessment of their health status (1,31). For this reason exercise testing soon after an acute event has become an accepted element of risk stratification and the measurement of functional work capacity (1,13,15,31). The diffusion of exercise testing has emerged as a convenient tool to gauge physical fitness, and, by extension, improve physical work capacity subsequent to exercise training (117). Thus, evaluating the progress of patients with coronary heart disease can now be accomplished functionally, anatomically by various angiographic and perfusion techniques, electrophysiologically, and prognostically.

Many generic issues common to the management of all chronic disabling illnesses are germane to the rehabilitation of patients with atherosclerotic ailments. There is intuitive logic behind the prescription of behavioral interventions to assist both patient and family in adapting to disability, prevention of complications, and avoidance of progression while restoring function. Nevertheless, there is a dearth of scientific evidence that might indicate the most effective components of such an effort, their optimal configuration, and the appropriate intensity or duration of therapy.

Aggressive control of risk factors for coronary disease is a frequent ingredient of cardiac rehabilitation services (1,18,37). However, debate continues around the influence on risk factors of such basic topics as the significance of weight reduction, smoking cessation methods, and the importance of dietary change (1,24,121,122). Debate also exists regarding the best method to promote mental health in patients and family members as well as how to increase long-term compliance with medically prescribed therapy such as exercise.

At this time there is no documentation that exercise therapy, as it is generally practiced, can alter myocardial lesions, improve perfusion, or stimulate the generation of collateral vessels in humans with coronary heart disease. There exists some evidence that sustained, intense endurance exercise may have a beneficial effect on left ventricular function, possibly mediated by an influence on the level of plasma catecholamines (28,76,77,80).

We are left with a large body of data that convincingly supports the ability of exercise training to increase functional work capacity in both healthy individuals and patients with diagnosed coronary heart disease (15). This represents an increase in physical fitness that permits a greater amount of physical function at the same level of cardiac exertion. In effect, the patient's exertion threshold for developing ischemic signs and symptoms is raised through the more efficient use of oxygen by adaptations of the peripheral skeletal musculature. A decrease in serum triglycerides has also been attributed to exercise, but its effect on total cholesterol levels is uncertain (1). The psychological impact of a cardiac event or symptoms can be highly disruptive. There is reason to believe that supervised exercise

therapy can serve to reassure the patient concerning the performance of normal daily activities, employment, and appropriate recreation (19). This would also serve to reduce disability and maintain vocational status.

Selection of patients for cardiac rehabilitation has generally tended to favor individuals with an uncomplicated acute myocardial infarction, those having had successful CABG surgery, or those with stable angina. Since an exercise prescription can be written with considerable flexibility, there are no hard and fast guidelines as to the minimum level of intensity that might exclude patients from participation. Prescribing of regimens is usually done on the basis of symptom-limited exercise testing as has already been described. Contraindications for participation in exercise therapy parallel those for exercise stress testing (118). Included are: unstable angina, severe ventricular dysfunction, active cardiomyopathy or myocarditis in the previous year, uncontrolled hypertension, complex dysrhythmias, second- and third-degree A-V block, uncontrolled atrial fibrillation, substantial cardiomegaly, valvular or cogenital heart disease with hemodynamic effects, and possible noncardiac illnesses.

Three to five weekly exercise sessions of about 1 hour each have been proposed as an appropriate level of activity to derive functional benefits (117,119). Many authors have suggested a course of 12 weeks of training extending from about 3 weeks or more after the cardiac event. Phase I, or in-hospital rehabilitation would commence at an earlier point.

Since Phase III of cardiac rehabilitation is pursued independently and extends indefinitely after adequate physical conditioning has been achieved, it is presumed that the need for supervision will have decreased. Progress may be followed with continued medical care and periodic exercise testing (1).

Electrocardiographic monitoring appears to provide a degree of safety during exercise therapy (97). Its utilization tends to be linked inversely with the cardiac stability of the patient, but no firm predictors exist which precisely identify those who might completely dispense with its use. Given the variable occurrence of arrhytmias and the fact that the safety of exercise regimens has only been determined by means of aggregate data, the use of continuous or intermittent monitoring for a specific patient remains a matter of clinical judgment (118). There are insufficient data to resolve the issue at this time.

The Council on Scientific Affairs of the American Medical Association (AMA) reviewed physician-supervised cardiac rehabilitation in 1981 (118). It was concluded that:

1. Exercise training can improve the objective and subjective rehabilitation of some patients with coronary heart disease and result in increased functional capacity.
2. Physician direction and supervision of exercise programs are critical to the proper assimilation of these services into the health care system.
3. Exercise testing is important for prescribing and then monitoring exercise rehabilitation programs in such patients and may provide prognostic information. Serial testing may help to individualize the length of the exercise program.
4. While rehabilitation programs appear to provide many subjective benefits to the cardiac patient, they have not yet been shown to improve survival.

5. Cardiac rehabilitation should be considered one of the treatments for coronary heart disease complementary to drug therapy or surgery.
6. Further studies that examine the long-term benefit of the different types of exercise programs are indicated.

The Diagnostic and Therapeutic Technology Assessment (DATTA) program of the AMA provided the Office of Health Technology assessment (OHTA) an opinion on cardiac rehabilitation services in 1986 (unpublished). Prescribed programs of exercise were considered "to be established as a safe and effective treatment for reduction of morbidity in patients with postmyocardial infarction, postcardiovascular surgery or with ischemic heart disease." The effect of prescribed exercise on mortality was stated to remain unproven. Phase I programs of early predischarge rehabilitation were considered "established as safe and effective therapy for reduction of morbidity on patients following myocardial infarction and cardiovascular surgery." Telemetry electrocardiographic monitoring during exercise regimens was stated to be "established as essential to the safety and efficacy of a prescribed exercise regimen." The value of telemetric monitoring in adjusting therapy was noted, but no consensus was reached on the optimal duration of continuous monitoring.

The American Heart Association (AHA) and its affiliates have expressed a favorable view of cardiac rehabilitation through several channels (31,119). A joint AHA/American College of Cardiology task force issued an unpublished position paper on the subject in 1983. It was concluded that "those patients who are willing to undertake exercise training should be encouraged to do so since the available evidence from epidemiological and clinical studies indicates that exercise training as part of cardiac rehabilitation reduces

subsequent morbidity and mortality." Standards for cardiovascular exercise treatment programs were produced by the AHA Subcommittee on Rehabilitation Target Activity Group in 1979 (31). A posthospital program that extends for 3-12 weeks was endorsed with monitoring during one of every three sessions. Up to 6 months of physical reconditioning was proposed as an adequate course for most patients with coronary heart disease. The Los Angeles affiliate of the AHA issued Guidelines for Cardiac Rehabilitation Centers in 1982 (119). A total of 12 weeks of supervised Phase II rehabilitation was proposed with one to three supervised sessions per week. It was emphasized that patient care remains the responsibility of the referring physician with the rehabilitation center fullfilling an adjunctive role. The frequency of monitoring was considered an element of the exercise prescription to be individualized for each patient.

The American Physical Therapy Association has provided OHTA materials for this assessment and issued an unpublished 1985 statement endorsing cardiac rehabilitation: "Cardiac rehabilitation provided by physical therapists and other qualified practitioners is a valuable and effective therapeutic component of medical care. Cardiac rehabilitation not only addresses medical necessity, but transcends into the medical-social factors that either cause or prevent incidence of coronary disease." A total of 10-14 weeks of progressive, supervised exercise training was deemed desirable with up to 18 months of regular independent exercise advised with periodic professional supervision during the later periods. Continuous telemetric monitoring on a routine basis was not endorsed after one to three initial exercise sessions. A case-by-case approach was recommended with one visit per month set aside to monitor long-term followup patients.

The American Occupational Therapy Association in a letter to OHTA endorsed cardiac rehabilitation services in 1985. It was stated that "this type of rehabilitation is a much needed medical service for individuals who have suffered heart attacks or have chronic heart disease and for those who have had coronary bypass surgery. Occupational therapy personnel, with their diversified medical and psychological training, are invaluable members of the cardiac treatment team."

YMCAardiac Therapy has submitted their manual, which was prepared for community groups wishing to organize cardiac rehabilitation programs in conjunction with YMCA facilities (37).

A statement provided to OHTA was developed by the ad hoc Task Force on Cardiovascular Rehabilitation of the American College of Cardiology in November of 1985, is as follows:

> Cardiovascular rehabilitation services can safely and effectively improve the functional and/or symptomatic status of patients with disorders related to cardiovascular disease. Such services can also reduce risk factors associated with atherosclerotic and hypertensive cardiovascular disease. Many patients are able to reduce the amount and number of medications as a result of these services. However, since the impact of rehabilitation programs on mortality is less well defined, in an aging population with a high incidence of cardiovascular disorders, the demand for cardiovascular rehabilitation programs is escalating at a time when dollar support is declining. Since ECG monitoring is the most costly of the services provided by these programs, it becomes imperative to redefine the role of the services provided, including ECG monitoring. The main purpose of cardiac rehabilitation at least should be to improve functional status.

The American Association of Cardiovascular and Pulmonary Rehabilitation submitted to OHTA scientific materials for consideration in performing this assessment. A 1985 statement of the Association's position is as follows:

> Like any medical therapy, the necessity to evaluate cardiac rehabilitation services as to its need, efficacy and clinical value is important. Although exercise therapy is one of the important services provided in cardiac rehabilitation programs, other services

such as smoking cessation, dietary assessment and modification, stress management, vocational counseling have equal value for many patients and clearly, the practice of cardiac rehabilitation in our society encompasses a variety of important services. Thus, any definition of evaluation of a medical service should include all of its important components.

Cardiac rehabilitation is defined as the active and progressive process by which individuals are restored to their optimal physical, medical, psychological, social, emotional, vocational and economic status. The total approach includes measures to prevent, retard or reverse the underlying coronary artery disease (CAD) processes. As such, the cardiac rehabilitation process involves a multidisciplinary health care team including physicians, behavioralists, nurses, exercise physiologists, nutritionists, physical and occupational therapists, vocational rehabilitation specialists and other allied health professionals. This health care team, which includes the primary physician, assesses and manages the needs of patients with cardiovascular disease in an effort to bring about the goals of the cardiovascular rehabilitation program within a defined period of time.

A statement in support of cardiac rehabilitation programs was submitted to OHTA by the American Nurses' Association in November of 1985. Their position was summarized as follows:

Cardiac rehabilitation is a collaborative approach to patient care in which the goal is to help patients with cardiovascular diseases, such as survivors of a myocardial infarction, achieve their optimal physical, emotional, social and vocational potential. Nurses are a part of the multidisciplinary health care team that assists patients to return to their previous roles or adapt to new ones. Moreover, outpatient cardiac rehabilitation programs, which generally consist of three sessions per week for 12 weeks, are usually under the supervision of registered nurses who manage cardiac rehabilitation programs. Nurse-managers coordinate the patient's care because of their link between the patient and other disciplines. It is in these dual roles of direct provider and coordinator of care that nurses are able to observe and assess the benefit of cardiac rehabilitation services for their patients.

The New York County Medical Society has submitted to OHTA a position statement on cardiovascular exercise training programs that was approved by their board of directors in 1983. It states in part: "Given the current understanding of the benefits and limitations, the New York County Medical Society supports planned, physician-directed and responsible rehabilitation

programs such as have been proposed and studied by various medical organizations in the United States." Certain facility safeguards were suggested including "That there be continuous monitoring during the entire exercise period in patients felt to be vulnerable to cardiac arrhythmias."

The Veterans Administration (VA) has responded to OHTA's request for information with a statement dated February 7, 1986. It was noted that "Exercise Rehabilitative Services constitute routine medical practice in the VA but are not standardized. With rare exception, all patients who have had a major cardiac health event (medical or surgical) are recommended for such rehabilitative care." A defined VA rehabilitation program for stable angina pectoris is not available. Overall, these exercise rehabilitation services were considered safe and effective with many patients returned to gainful occupation at a relatively early stage after adverse events. Occupational therapy and psychotherapy are included where indicated.

The Food and Drug Administration had no comment on this assessment since exercise rehabilitative therapy does not come under its purview.

Information was received from the National Institutes of Health (NIH) concerning cardiac rehabilitation services in November of 1985. The complexity of such programs was emphasized in view of the diversity of patient physiologic needs and capacities, life styles, and behavioral and attitudinal state. In addition, NIH cited the "difficulty or almost impossibility of firm quantification of the many clinically significant results." The present coverage statement found in Chapter II, Section 35-25, of the Medicare Coverage Issues Appendix was considered "reasonably good." However, "continuous electrocardiographic monitoring during exercise at reasonable prescribed work levels is necessary only in exceptional cases." Overall, programs for cardiac rehabilitation were considered by NIH to be a standard

practice in the management of the patient with coronary heart disease. NIH found that there is now sufficient data to accept the usefulness of cardiac rehabilitation, but the scientific basis "remains fragile."
Notice of this assessment appeared in the Federal Register of August 15, 1985, Vol. 50(158):32911-32912.

SUMMARY

Cardiac rehabilitation services are intended to restore certain patients with coronary heart disease to active and productive lives. A comprehensive long-term program of medical evaluation and management, prescribed exercise, cardiac risk factor reduction, education, and counseling is encompassed. Cardiac rehabilitation programs have occasionally enrolled patients with other forms of heart disease, or asymptomatic individuals with elevated risk factors for coronary heart disease. Nevertheless, cardiac rehabilitation services are typically intended for patients recovering from an acute myocardial infarction, CABG surgery, or with chronic stable angina pectoris.

Prescribed therapeutic endurance exercise regimens are central to virtually all programs. Patients with uncomplicated coronary artery disease are exercise tested for prognostically important exercise-induced variables such as angina, ST-segment deviation, heart rate, and blood pressure response preparatory to enrollment. There is some controversy as to how soon after an acute cardiac event exercise testing may be done. However, there is evidence that the results of symptom-limited exercise tests in the 3 months after an uncomplicated myocardial infarction are reliably reproducible. Uncomplicated cases are considered to be patients without serious or recurrent arrhythmias, shock, persistent pain, or congestive heart failure. Generally, graded

exercise testing 1-3 weeks or more after an acute event has been recommended to establish a patient's activity limits, provide prognostic information, and derive an exercise prescription.

Cardiac rehabilitation services are customarily divided into three phases. Phase I is inpatient rehabilitation activities that begin during hospitalization and extend until discharge. Phase II is a supervised ambulatory outpatient period that follows discharge and extends until the patient becomes sufficiently independent to perform prescribed exercise and carry out recommended long-term lifestyle changes. Phase III is a lifetime maintenance stage in which physical fitness and cardiac risk factor reduction are accomplished in an unsupervised (or minimally supervised) setting. Phase II, the supervised program, usually extends for about 3-6 months after an infarction, CABG surgery, or other event.

The organization of comprehensive Phase II cardiac rehabilitation programs may involve exercise groups of differing size and monitoring practices. There is a preponderance of opinion in the literature that programs should be medically directed with trained professional staff and equipment on hand to deal with arrhythmias and other emergent cardiac events on an immediate basis. Standards for cardiac rehabilitation centers have been drafted by several professional groups, but specific conditions of participation under Title XVIII of the Social Security Act currently do not exist. There is evidence that an average of three weekly, 1-hour training sessions for 12 weeks is sufficient to achieve reasonable physiologic benefit from prescribed exercise therapy in a Phase II program. If no benefit is measurable after 6 months, it is unlikely that an increase in functional capacity will be attained. No data are available concerning the optimal conditions for other nonexercise components of cardiac rehabilitation

capacity will be attained. No data are available concerning the optimal conditions for other nonexercise components of cardiac rehabilitation services.

There is general agreement that the principal physiologic benefit obtainable with exercise therapy is an increase in functional work capacity with a greater tolerance for exertion before the onset of angina or other signs and symptoms of coronary ischemia. There is no firm scientific basis at present to corroborate beneficial myocardial adaptation in response to exercise training at customary levels of training intensity among patients with coronary heart disease. Myocardial effects may, however, occur when selected low-risk patients are trained at sustained levels of higher intensity endurance exercise. The exact nature of such myocardial improvement is not currently known.

A consensus of opinion exists that cardiac rehabilitation services can safely improve the functional and symptomatic status of medically selected patients at relatively low risk for adverse cardiac events during exercise. The precise probability that a specific patient will or will not develop an exercise-induced complication remains uncertain. At this juncture, the formulation of an exercise prescription based on submaximal myocardial workload, determined by exercise testing, represents the best supplement to the clinical judgment of the attending physician that is available. In principle, medical supervision of exercise therapy should be in direct relationship to the risk status of the patient. In practice, exercise training is generally contraindicated for cardiac patients who are clinically unstable or with contravening noncardiac complications.

Many low-risk cardiac rehabilitation patients can successfully and safely undergo exercise therapy on an independent basis in their homes or in large supervised community group programs. The use of continuous electrocardiographic monitoring during exercise represents a safeguard of unknown dimensions. There is evidence that it may reduce the aggregate rate of cardiac complications, but there is also evidence that monitoring may be safely used on an intermittent basis during exercise training. Periodic transtelephonic monitoring of electrocardiographic data has been used to follow some low-risk patients training at home. Again, the judgment of the responsible physician is the determining influence since many complex clinical factors must be evaluated. Guidelines have been suggested by various professional groups to govern the use of continuous monitoring, but such rules tend to be of a general advisory nature. In the last analysis, continuous monitoring has been recommended for high-risk patients, however such distinctions are clinically inexact in this context.

Cardiac rehabilitation services are considered safe and efficacious therapy to improve the cardiovascular and psychosocial status of patients with documented coronary heart disease to the extent that it improves exercise tolerance or otherwise enhances functional capacity. No evidence exists to indicate that cardiac rehabilitation improves prognosis in patients with coronary artery disease. Patients with a recent acute myocardial infarction, CABG surgery, and stable angina pectoris are among those who have benefited from this technology.

Prepared by: Ernest Feigenbaum, M.D.

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16. Abstract (Limit: 200 words)

Cardiac rehabilitation services are comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. These programs are designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or reinfarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients. Cardiac rehabilitation services are prescribed for patients who (1) have had a myocardial infarction; (2) have had coronary bypass surgery; or (3) have chronic stable angina pectoris. The services are in three phases beginning during hospitalization, followed by a supervised ambulatory outpatient program lasting 3-6 months, and continuing in a lifetime maintenance stage in which physical fitness and risk factor reductions are accomplished in a minimally supervised or unsupervised setting. There are no uniform standards for these services. Data suggest that three weekly 1 hour exercise sessions for 12 weeks yield physiologic benefits. Routine electrocardiographic monitoring during exercise is necessary only in exceptional cases. A consensus of opinion suggests that these programs improve the function and symptomatic status of selected patients and are associated with little risk of adverse events.

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